Unpacking the black box: theory-based design & evaluation of a multiple behaviour change intervention to control diarrhoeal disease

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Declaration

I, Catherine Elizabeth Greenland, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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14 February 2017

Acknowledgments

Journeying to and from Zambia over the years has frequently taken me through Johannesburg airport. The words of a famous African proverb displayed prominently in the departures hall come to mind now:

"If you want to go fast, go alone. If you want to go far, go together."

No large piece of research can – or indeed should – be done alone. My first expression of thanks goes to my Supervisor, Val Curtis, for her continual support and belief in my abilities throughout this project. I am also extremely grateful to all the excellent researchers who have advised me officially in different capacities over the past three years: Adam Biran, Roma Chilengi, Zelee Hill, James Lewis, Wolf-Peter Schmidt and Barbara Willey. I am particularly indebted to Adam Biran for his counsel and encouragement as I juggled my PhD research with other work commitments. I am also thankful to many others at LSHTM and elsewhere who have contributed time and expertise at various points during my research and the writing of this thesis, namely: Bob Aunger, Azie Berhane, Clare Chandler, Oliver Cumming, Jeroen Ensink, Andy Haines, Gaby Judah, Margaret Manly, Crispen Sachikonye, Belen Torondel, Helen Travaskis and Sian White. Thanks are also owed to James Hargreaves and Joanna Schellenberg for examining my Upgrading from MPhil to PhD and for encouraging me to critically reflect on and narrow the scope of my research. To colleagues past and present in the Environmental Health Group and in room 441: thank you for being part of my journey.

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The collective provision of laughter and a dose of 'perspective' from family and friends have brought me to this point. Thank you to my friends in Zambia and the UK, in particular Yael Velleman, who built my confidence with tea, cake and her wise words. Thanks also to my loving and supportive family, for putting up with endless conversations about faeces over the dinner table. The same thanks and more go to my wonderful husband, Tim: thank you for always being at the other end of the phone when I was in Zambia and for keeping me fed and watered as I wrote my thesis in the first few months of our marriage. Dad, when you fell ill I asked you what you thought I would do with my life, to which you replied: *"You are a big girl Katie, I think you can figure that out for yourself"*. Making you proud has always made every achievement sweeter. You always thought that I would do a PhD one day and I know that you are proudly watching down on me now.

Abstract

Handwashing with soap, exclusive breastfeeding and the use of oral rehydration salts and zinc to manage diarrhoea episodes are apparently simple practices through which many child deaths from diarrhoea could be prevented. However, their success depends on caregiver behaviour, which has proved difficult to influence. This thesis describes the development and evaluation of a theory-based, multiple behaviour change intervention to improve uptake of these diarrhoea control practices in Lusaka Province, Zambia.

The research was guided by a conceptual framework based on an ecological theory of behaviour and comprised three studies: formative research, outcome evaluation and process evaluation. Formative research focussed on actual practices of target behaviours and their determinants and informed the design of an intervention based on the motive *affiliation*. Outcome evaluation used a cluster-randomised trial to assess the effect of the intervention on handwashing with soap, exclusive breastfeeding, and use of oral rehydration salts and zinc to manage childhood diarrhoeal episodes. The intervention resulted in a small improvement in reported practice of exclusive breastfeeding. Changes in the other target behaviours were observed in areas where higher reach was achieved. The process evaluation used mixed methods and was guided by the intervention's theory of change to explore how intervention content and delivery influenced behavioural outcomes. The process evaluation revealed that the intervention was popular and memorable, but it achieved low and variable levels of reach and did not change psychological mediators of behaviour.

This research adds to the currently small evidence base in the field of multiple behaviour change for diarrhoea control. In light of the findings of low reach, further work is needed to ascertain whether delivery alone is the issue, or whether the intervention content also requires revision. The findings underscore the importance of modifying intervention delivery strategies to account for the local context.

Contents

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Abbreviations

Centre for Infectious Disease Research in Zambia (CIDRZ)

Cluster-Randomised Trial (CRT)

Confidence Interval (CI)

Demographic and Health survey (DHS)

Disability-Adjusted Life Years (DALYS)

Global Enteric Multicenter Study (GEMS)

Human Immunodeficiency Virus (HIV)

Integrated Management of Childhood Illnesses (IMCI)

Intra-Cluster Correlation Coefficient (ICC)

London School of Hygiene and Tropical Medicine (LSHTM)

Medical Research Council (MRC)

Neighbourhood Health Committee volunteers (NHCs)

Oral Rehydration Salts (ORS)

Oral Rehydration Therapy (ORT)

Principal Component Analysis (PCA)

Programme for the Awareness and Elimination of Diarrhoea (PAED)

Socio-Economic Status (SES)

United Nations Children's Fund (UNICEF)

Water, Sanitation and Hygiene (WASH)

World Health Organisation (WHO)

PART I

Introduction and Background

Chapter 1: Introduction and Background

1.1 Introduction to thesis

Diarrhoea remains the second largest cause of death among children under-five in Africa. The vast majority of these deaths are preventable using simple and effective solutions. However, the full potential of existing interventions cannot be realised without a large numbers of caregivers complying with recommended practices. Behaviour change interventions seek to encourage uptake of 'healthy' behaviours, but behaviour change is notoriously challenging and interventions often fail. In order to improve intervention effectiveness, innovative approaches need to be tested to explore what works, for whom, and under what conditions. This thesis reports on the design and evaluation of a multiple behaviour change intervention to control childhood diarrhoea in Lusaka Province, Zambia.

1.2 Overview of chapter

In this chapter, I provide an introduction to diarrhoeal disease and give an overview of the evidence-base for recommended control strategies. I also provide some contextual information on diarrhoea control in Zambia and outline the origin of the research presented in this thesis. The chapter concludes with a description of the thesis structure and my role in the research included in this thesis.

1.3 Epidemiology of childhood diarrhoea

1.3.1 Global burden of disease

Globally, the number of children dying before their fifth birthday has declined substantially since the 1950s (Ahmad et al., 2000, You et al., 2015). This has been attributed largely to improvements in the prevention and treatment of infectious diseases such as pneumonia, diarrhoea, measles and malaria (Liu et al., 2015). Although diarrhoea mortality has reduced greatly (Liu et al., 2016), diarrhoea

morbidity has remained relatively stable over time (Fischer Walker et al., 2012, Lamberti et al., 2012). The decline in mortality is often attributed to improved clinical case management of diarrhoea, as a result of the introduction and scale-up of oral rehydration therapy during the 1980s and 1990s (Victora et al., 2000, Santosham et al., 2010). Increasing rates of child survival in highly-populated areas such as India and China have also had a significant impact on global statistics (Liu et al., 2015). Despite these gains in child survival, an estimated 9% of the 5.9 million child deaths in 2015 were caused by diarrhoea, making it the single largest cause of post-neonatal child mortality after pneumonia (You et al., 2015). Diarrhoea continues to cause severe morbidity (Fischer Walker et al., 2013), burdening the economy (Hutton et al., 2007, Tate et al., 2009, Townsend et al., 2017) as well as public health. The need for continued investment to improve control efforts is evident.

The global diarrhoea burden is unequally distributed: 82% of diarrhoea mortality occurs in just two regions, South Asia and Sub-Saharan Africa (Fischer Walker et al., 2013). Sub-Saharan Africa is particularly affected: it accounts for only 21% of the global population of under-fives, but 50% of the world's child diarrhoeal deaths (Fischer Walker et al., 2013). Figure 1-1 shows the unequal geographical distribution of deaths among children under-five attributable to diarrhoea in 2015.

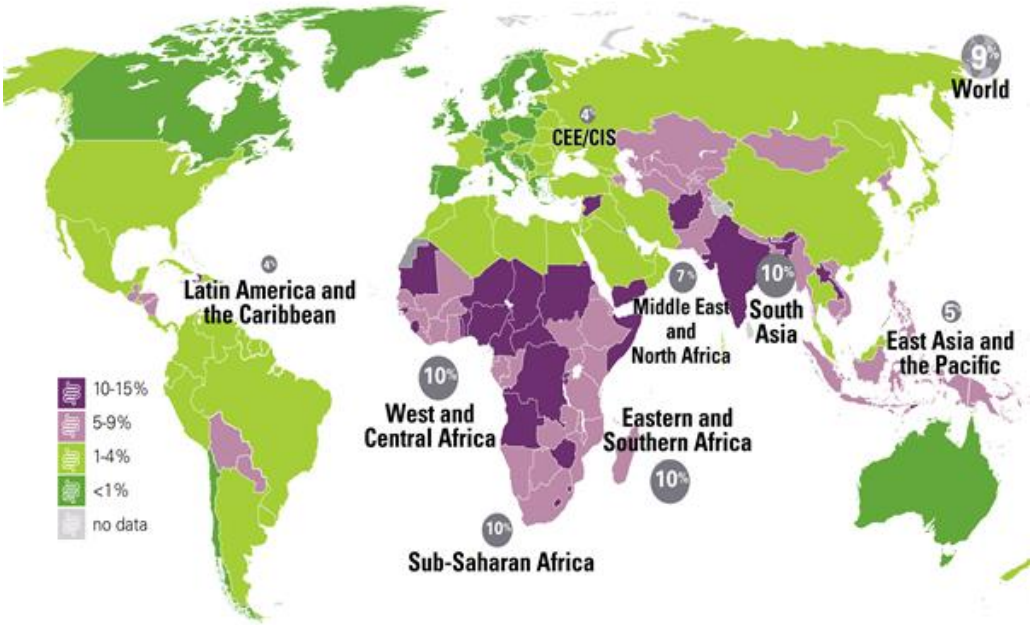

Figure 1-1. Global distribution of deaths among children under-five attributable to diarrhoea, 2015, reproduced from (UNICEF, 2016a)

Disparities in diarrhoea morbidity and mortality occur within countries as well as between them. In general, the most vulnerable children in any given country bear the highest burden of disease: around 80% of child deaths from diarrhoea occur in the first two years of life (Fischer Walker et al., 2013). This is the time when children are the most susceptible to infection and at the greatest risk of dehydration (Keusch et al., 2016). Children in low-income households are also more susceptible to diarrhoea and are more often at risk of negative outcomes following a diarrhoeal episode (Keusch et al., 2016). Children infected with Human Immunodeficiency Virus (HIV) are also more vulnerable than other children; they are more likely to suffer from persistent diarrhoea (lasting 14 days or longer) and 11 times more likely to die than uninfected children (Tindyebwa et al., 2006).

1.3.2 Aetiology and sequelae

An estimated 4.7 million episodes of diarrhoeal disease occur globally each day (Fischer Walker et al., 2013). For each child under-five living in South Asia and Sub-Saharan Africa, this translates to an average of 2.7 episodes each year (Fischer Walker et al., 2012). Up to 2% of these diarrhoeal episodes are estimated to be severe (Lamberti et al., 2012, Fischer Walker et al., 2013), which can result in a 9-fold increase in the odds of dying following an episode of diarrhoea (Kotloff et al., 2013).

Some pathogens are more commonly associated with severe diarrhoea than others, although the specific aetiology is rarely confirmed. In a study conducted at seven sites across South Asia and Sub-Saharan Africa - The Global Enteric Multicenter Study (GEMS) – Kotloff and colleagues compared cases of moderate-to-severe diarrhoea among children under-five presenting at health centres with matched, healthy controls (Kotloff et al., 2013). The study found that four pathogens were responsible for the majority of moderate-to-severe diarrhoea cases in all study sites: rotavirus, *Cryptosporidium*, enterotoxigenic *E. coli*, and *Shigella*. Recent reanalysis of these same data using more advanced quantitative molecular diagnostic methods identified two additional pathogens of importance: adenovirus 40/41 and *Campylobacter* (Liu et al., 2016). Improved knowledge of the aetiology of severe diarrhoea from GEMS will be important for deciding the most effective interventions for diarrhoea treatment and control in a given setting.

GEMS also corroborated the findings of others (Checkley et al., 2008) concerning the longer-term effects of diarrhoea on undernutrition. Cases were more likely to experience linear growth faltering (stunting) during the 60-day follow-up period than controls, despite comparable height-for-age scores at enrolment (Kotloff et al., 2013). This is important because malnutrition is associated with half of all child deaths (Rice et al., 2015) and has been demonstrated to be an important underlying cause of deaths from diarrhoea (Caulfield et al., 2004, Black et al., 2008).

Arguably more important than the direct contribution of diarrhoea to undernutrition are the hypothesised impacts mediated through environmental enteric enteropathy, a common disorder of the small intestine that affects nutrient absorption (Humphrey, 2009, Prendergast and Kelly, 2012, Keusch et al., 2016). Environmental enteric enteropathy is thought to be associated with chronic exposure to gastrointestinal pathogens (Prendergast and Kelly, 2012) as enteropathy is commonly seen among individuals living in environments that are heavily contaminated with faecal pathogens (Prendergast and Kelly, 2012, Lin et al., 2013). Crucially, GEMS demonstrated that asymptomatic infection with faecal pathogens is common: a high proportion of the controls were also infected (Kotloff et al., 2013). It is therefore likely that interventions that interrupt diarrhoea will have a wider impact on child survival and development beyond the direct impact on diarrhoea morbidity and mortality.

1.3.3 Faecal-oral transmission routes

This section reviews the main routes of transmission of organisms causing diarrhoea. One gram of human faeces can contain up to 10^9 infectious viral particles and a million bacterial pathogens (Feachem et al., 1983a). Most diarrhoea is caused by infection with bacteria, viruses or protozoa which have been transmitted through faecal-oral routes from an infected individual. If a susceptible individual ingests faecal pathogens in sufficient quantities they become infected. 'Faecal-oral' transmission can occur via at least five pathways illustrated by the classic 'F-diagram' developed by Wagner and Lanoix in 1959 shown in Figure 1-2.

If excreta is not disposed of safely, faecal pathogens in the environment can enter the mouth directly through hands that have been in contact with faeces, or indirectly via contaminated foods or water (**F**luids). **F**ood can become contaminated with faecal pathogens in several ways: through the use of wastewater on crops (**F**ields / **F**loors), via the **F**lies that land on it, through water used to prepare it, or through the hands (**F**ingers) or utensils used to prepare and serve it.

The 'F diagram' also illustrates how faecal-oral transmission routes can be interrupted by water, sanitation and hygiene, collectively known as 'WASH' interventions. The scarcity of data makes it difficult to ascertain the relative importance of different transmission routes and this limits the ability to target control strategies to any particular pathway.

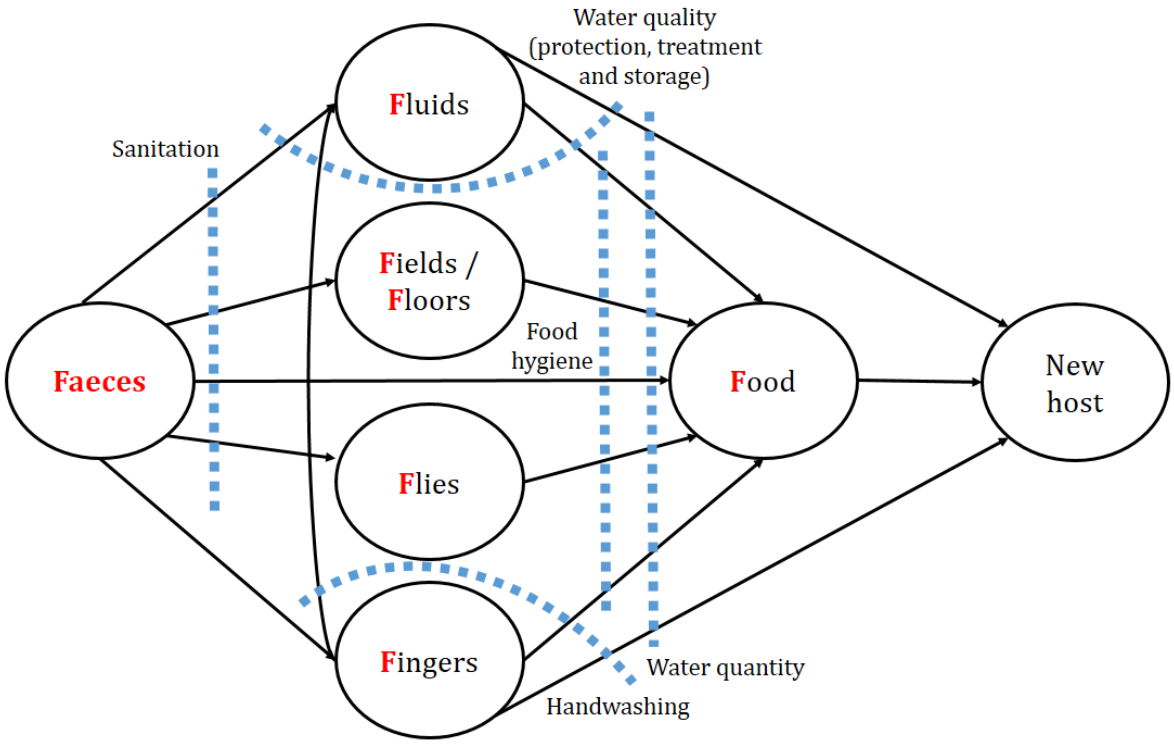

Figure 1-2. The F-diagram illustrating the main pathways of transmission for faecal pathogens and the interventions that can interrupt these pathways, adapted from (Wagner and Lanoix, 1959)

1.4 Control of childhood diarrhoea through the 7-Point Plan

Diarrhoea control involves WASH interventions, but also includes a suite of other measures. Diarrhoea can also be prevented through vaccination (against rotavirus and measles); a child's susceptibility to severe diarrhoea can be reduced through exclusive breastfeeding, vitamin A and zinc supplementation; and therapeutic interventions - including oral rehydration therapy through the use of Oral Rehydration Salts (ORS) solutions and zinc - can improve treatment outcomes. Collectively, these strategies form the '7-Point Plan' for comprehensive diarrhoea control proposed by United Nations Children's Fund (UNICEF) and the World Health Organisation (WHO) in 2009 (UNICEF/WHO, 2009) (Box 1-1).

Box 1-1. Diarrhoea control interventions comprising the '7-Point Plan', adapted from (UNICEF/WHO, 2009)

Prevention

Primary prevention to reduce disease transmission

- WASH interventions
  - Sanitation
  - Safe water
  - Handwashing with soap
- Vaccines (rotavirus and measles)

Secondary prevention to reduce disease severity

- Breastfeeding promotion
- Vitamin A supplementation
- Zinc

Treatment

- Oral rehydration therapy
- Zinc
- Continued feeding (including breastfeeding)

The list of recommended interventions has changed little from the control measures proposed more than 30 years ago by Feachem and colleagues (Feachem et al., 1983b). Even recent advances, such as the licensing of new vaccines, were predicted: their potential contribution to diarrhoea control was estimated to be substantial (de Zoysa and Feachem, 1985). Although the suite of control measures in use today is not new, the sector continues to innovate to make interventions more effective and to improve delivery. A major shift in global policy has also occurred in the last two decades, with vertical programmes focussed on diarrhoea control abandoned in favour of more integrated approaches to disease control (Santosham et al., 2010). While many diarrhoea control measures are also

important for the control of pneumonia and other diseases, for the purpose of this thesis, discussion is limited to the impact of interventions on diarrhoea morbidity and mortality.

1.4.1 Primary prevention to reduce diarrhoea transmission

WASH interventions and vaccination against rotavirus and measles are the primary methods for the prevention of diarrhoea. Reasons for the inclusion of each intervention are summarised in Table 1-1 and described in turn below.

Table 1-1. Summary of evidence supporting prevention of diarrhoea through WASH and vaccination

Intervention	Evidence for impact on diarrhoea
WASH	
Sanitation (safe disposal of human excreta)	28%-40% risk reduction (Fewtrell et al., 2005, Waddington et al., 2009, Cairncross et al., 2010b, Wolf et al., 2014) *Estimates may underestimate the true impact (Schmidt, 2015)*
Water quality (protection and treatment of water at the source or within the home)	*Household water treatment:* 17-42% (Fewtrell et al., 2005, Clasen et al., 2006, Waddington et al., 2009, Cairncross et al., 2010b) *Estimates may overestimate the true impact (Schmidt and Cairncross, 2009, Wolf et al., 2014)*
Water supply	*Provision of improved community water sources:* 11% (95% CI 0-22%) (Wolf et al., 2014) *High quality piped water:* 79% (95% CI 44%-92%) (Wolf et al., 2014)
Handwashing with soap	*Promotion of handwashing with soap:* 40% (95% CI: 32%-47%) (Freeman et al., 2014) *Hygiene education:* 24% (95% CI: 14%-33%) (Freeman et al., 2014) *Estimates do not account for potential bias and may thus overestimate the true impact (Freeman et al., 2014, Prüss-Ustün et al., 2014)*
Vaccination	
Rotavirus	*Pooled efficacy* of 51% in low-income countries (Jiang et al., 2010)
Measles	Responsible for 77% of childhood diarrhoea deaths pre-measles vaccination (Hussey and Clements, 1996)

1.4.1.1 WASH interventions

WASH interventions seek to interrupt both 'waterborne' and the more important 'water-washed' transmission of faecal-oral pathogens causing diarrhoea (White et al., 1972, Feachem et al., 1983a). Poor WASH is estimated to account for 58% of the total burden of diarrhoeal disease (95% Confidence Interval (CI): 48%-65%)

(Prüss-Ustün et al., 2014) and 5% of the total DALYS (Disability Adjusted Life Years) in 38 countries (GBD Risk Factors Collaborators et al., 2015).

Sanitation represents a primary barrier to faecal-oral transmission (Figure 1-2). However, in 2015, 946 million people globally defecated directly in fields, vacant spaces or water bodies (JMP, 2015). Despite differences in study quality and reported effect estimates, systematic reviews provide consistent evidence that sanitation can reduce diarrhoea risk by 28-40% (Fewtrell et al., 2005, Waddington et al., 2009, Cairncross et al., 2010b, Wolf et al., 2014). However, many sanitation interventions assessed in rigorous health impact evaluations have not achieved high coverage (Cameron et al., 2013, Clasen et al., 2014, Patil et al., 2014). As the benefits of sanitation may not be realised unless the majority of individuals in a community dispose of faeces safely (Hunter and Pruss-Ustun, 2016), the impact of sanitation estimated by systematic reviews may well be underestimated (Schmidt, 2015).

Water quality and quantity both play important roles in interrupting diarrhoea transmitted via the waterborne and water-washed routes. Household water treatment interventions are considered to be the most effective way of improving water quality (Clasen et al., 2006, Wolf et al., 2014), estimated to reduce the risk of diarrhoea by 17-42% (Fewtrell et al., 2005, Clasen et al., 2006, Waddington et al., 2009, Cairncross et al., 2010b). However, water quality studies suffer from bias introduced by lack of blinding and the use of subjective outcomes (Schmidt and Cairncross, 2009, Wolf et al., 2014). Furthermore, near perfect compliance is required to realise these benefits (Clasen et al., 2006, Brown and Clasen, 2012, Enger et al., 2013).

The benefits of better access to water are thought to stem mostly from the increased quantity of water that becomes available for hygienic purposes (personal and domestic) when distance to a water source decreases and the overall quantity of water collected increases (Cairncross and Cliff, 1987, Cairncross and Feachem, 1993, Pickering and Davis, 2012). The greatest benefits (79% reduction in diarrhoea risk; 95% CI 44%-92%) are associated with household provision of piped water connections with continuous, safe supply (Wolf et al., 2014). However, only 12% of the global population had piped water on their premises in 2015 (JMP, 2015). As water supply infrastructure can be very costly

and requires ongoing maintenance, sustainable service provision requires significant financial and human resources (Hutton and Chase, 2016).

Handwashing at key times - after risk of contact with faeces (after defecation and after changing a nappy or handling child faeces) and before handling food or drinking water -is a biologically plausible mechanism for interrupting the transmission of diarrhoeagenic pathogens (Curtis et al., 2011). Evidence from observational studies and randomised controlled trials consistently suggests that handwashing with soap can substantially reduce the risk of diarrhoea (Curtis and Cairncross, 2003, Ejemot et al., 2008, Bartram and Cairncross, 2010, Freeman et al., 2014, Ejemot-Nwadiaro et al., 2015). The latest review by Freeman and colleagues estimates that promotion of handwashing with soap prevents 40% of diarrhoea (95% CI: 32%-47%) and hygiene education prevents 24% of diarrhoea (95% CI: 14%-33%) (Freeman et al., 2014).

1.4.1.2 Vaccination

Diarrhoea can also be prevented through vaccination. However, since diarrhoea is caused by multiple agents, pathogen-specific vaccines are needed (Keusch et al., 2016). The only one of the leading causes of severe diarrhoea identified in the GEMS study (Kotloff et al., 2013, Liu et al., 2016) with a licensed vaccine is rotavirus (Das et al., 2013). In 2009, WHO recommended the global introduction of rotavirus vaccination (WHO, 2009). The decision was taken even though vaccine efficacy in low-income settings was much lower than that observed in high-income countries (pooled efficacy of 51%) (Jiang et al., 2010). In 2008, prior to the introduction of rotavirus vaccination, rotavirus caused around 40% of all child deaths from diarrhoea (Tate et al., 2012). As rotavirus has a very low infective dose (Bishop, 1996), WASH interventions can do little to interrupt transmission of rotavirus, so even a vaccine with low efficacy could have a large impact on the burden of disease (Esrey et al., 1985).

Rotavirus vaccines were included in the routine immunisation schedules in 37 low-income countries between 2011 and 2015 (Gavi [the Vaccine Alliance], 2015). However, assuring the supply of the vaccine and achieving high levels of coverage have been challenging (Gavi [the Vaccine Alliance], 2015). Rotavirus vaccination will have the greatest impact if it reaches the poorest children who are most at risk

of negative health outcomes following an episode of diarrhoea (Atherly et al., 2012, Rheingans et al., 2012). As concurrent enteric infections may limit the effectiveness of oral vaccines in areas with poor sanitary conditions (Levine, 2010, Serazin et al., 2010), coordinated delivery of vaccination and WASH interventions may provide even greater protection against diarrhoea.

Measles vaccination does not directly protect against diarrhoea, but diarrhoea is one of the main causes of death following measles (Hussey and Clements, 1996). Child death due to measles reduced by 79% between 2000 and 2014 as a result of vaccination (WHO, 2016). Coverage levels over 90% are required to achieve herd immunity (Fine, 1993). Before vaccination efforts were scaled up, measles accounted for 1-7% of all diarrhoeal episodes worldwide and was responsible for up to 77% of all childhood diarrhoea deaths (Hussey and Clements, 1996).

1.4.2 Secondary prevention to reduce diarrhoea severity

The negative health outcomes associated with diarrhoea can be reduced through methods of secondary prevention. These include (exclusive) breastfeeding and improved nutrition (vitamin A and zinc supplementation). The evidence for their inclusion in the 7-Point Plan (UNICEF/WHO, 2009) is summarised in Table 1-2 and the text below.

Table 1-2. Summary of the evidence supporting prevention of severe outcomes of diarrhoea through exclusive breastfeeding and improved nutrition

Intervention	Evidence for impact on diarrhoea
(Exclusive) breastfeeding	Breastfeeding reduces diarrhoea incidence (Lamberti et al., 2011) and promotes recovery during illness (Kramer et al., 2001) Infants not breastfed are 10.5 times more likely to die from diarrhoea than infants exclusively breastfeed for 0-5 months (95% CI: 2.8–39.6) (Lamberti et al., 2011)
Vitamin A supplementation	28% reduction in diarrhoea mortality (95% CI: 9%-43%) (Mayo-Wilson et al., 2011)
Zinc supplementation	18% non-significant reduction in mortality (Relative risk 0.82; 95% CI: 0.64–1.05) (Yakoob et al., 2011) 13% reduction in incidence (95% CI: 6%-19%) (Yakoob et al., 2011)

1.4.2.1 Exclusive breastfeeding

WHO defines exclusive breastfeeding as giving no food or drink, including water, other than breast milk and recommends this for the first six months of life (WHO, 2001, WHO, 2003). This applies for all infants in all settings, regardless of maternal Human Immunodeficiency Virus (HIV) infection status (WHO, 2010). Breastfeeding can reduce diarrhoea incidence (Lamberti et al., 2011), but it also promotes recovery during illness (Kramer et al., 2001) and thus reduces the consequences of diarrhoea, including mortality (Lamberti et al., 2011). This is why it is termed a secondary mode of prevention. Lamberti and colleagues' meta-analysis of 18 studies found that infants that were not breastfed were 10.5 times more likely to die from diarrhoea than infants exclusively breastfed for 0-5 months (95% CI: 2.8–39.6) (Lamberti et al., 2011). Their review also demonstrated the substantial incremental benefits of exclusive breastfeeding over partial and even predominant breastfeeding.

In 2001, WHO recommended that infants should be exclusively breastfed for six months, a change from the earlier advice to breastfeed exclusively for 4-6 months (WHO, 2001). This recommendation was based on expert opinion and the findings of a later-published systematic review on the optimal duration of exclusive breastfeeding (Kramer and Kakuma, 2002). However, the authors of this review also stated that *"larger sample sizes would be required to rule out small increases in the risk of undernutrition"* (Kramer and Kakuma, 2002). The lack of conclusive evidence concerning the benefits of exclusive breastfeeding infants 0-5 months-of-age has prompted ongoing debate about the decision to increase the recommended duration of exclusive breastfeeding (Fewtrell et al., 2007). Nevertheless, as infants who are exclusively breastfed for at least six months have been shown to have significantly fewer episodes of diarrhoea than infants exclusively breastfed for three or four months (Kramer and Kakuma, 2002, Kramer and Kakuma, 2012), the argument for exclusively breastfeeding for six months is compelling with regard to diarrhoea. The challenge is to encourage mothers to comply with these recommendations: only 34% of infants 0-5 months-of-age in low-income countries are exclusively breastfed (Bhutta and Labbok, 2011).

1.4.2.2 Vitamin A and zinc supplementation

The WHO/UNICEF 7-Point Plan also recommends dietary supplementation with vitamin A and zinc (UNICEF/WHO, 2009). Vitamin A is required for the maintenance of many bodily functions. Vitamin A supplements given to pregnant and breastfeeding mothers and to children under-five have multiple public health benefits (Ross, 2002, Imdad et al., 2010). Vitamin A supplementation is associated with reductions in all-cause child mortality of up to 30% (Beaton et al., 1993, Fawzi et al., 1993, Glasziou and Mackerras, 1993, Mayo-Wilson et al., 2011), including a 28% reduction in deaths from diarrhoea (95% CI: 9%-43%) (Mayo-Wilson et al., 2011). Vitamin A reduces diarrhoea mortality because it reduces episode duration and severity (Barreto et al., 1994, Bhutta et al., 1999) through its actions on the immune system and role in the renewal of intestinal epithelia during and after an episode of diarrhoea (Bhan and Bhandari, 1998).

Zinc appears twice in the 7-Point Plan: as a dietary supplement to protect against severe disease, and as a treatment for all types of diarrhoea. Therapeutic use of zinc in the management of diarrhoea is discussed in the next section. Zinc is important for child growth and development, and for the normal functioning of cells and the immune system (Wessells and Brown, 2012, Prasad, 2013). Zinc is most efficiently obtained from foods such as fish and meat. As zinc-rich foods are expensive and zinc is not stored in the body, zinc deficiency is common in children from poor households in low and middle income countries (Lazzerini, 2014). An estimated 20% of children worldwide are at risk of zinc deficiency (Bhutta et al., 2013).

Dietary zinc supplementation acts as a prophylactic, although the mechanism by which zinc prevents diarrhoea and other infections is not fully understood (Prasad, 2013). Although findings from individual studies show considerable heterogeneity in impact, over the years, a number of systematic reviews have demonstrated that zinc supplementation can reduce diarrhoea incidence among children with impaired nutritional status (Bhutta et al., 1999, Aggarwal et al., 2007, Mayo-Wilson et al., 2014). Yakoob and colleagues estimated parameters for inclusion in the 'Lives Saved Tool', concluding that zinc supplementation is associated with a non-significant reduction in mortality from diarrhoea of 18% (Relative risk 0.82; 95% CI: 0.64–1.05) and a 13% reduction in incidence (95% CI: 6%-19%) (Yakoob et al.,

2011). It has been estimated that dietary supplementation with zinc could be more cost-effective than zinc treatment (Brown et al., 2013), although this estimate is based on the difficulties associated with increasing coverage of zinc treatment, rather than the relative health benefits.

Identification of effective policies (Aguayo and Baker, 2005) and efficient delivery routes are critical to the scale up of micronutrient supplementation interventions (Wazny et al., 2013).

1.4.3 Diarrhoea treatment

A further way to control diarrhoea and prevent mortality is prompt and effective treatment. Inflammatory and bloody diarrhoea caused by some bacterial pathogens need to be treated with antibiotics (Keusch et al., 2016). However, diarrhoea-associated deaths are usually due to the dehydration caused by loss of water and electrolytes. The mainstay of treatment involves uses of ORS solutions and zinc. The evidence for the impact of these interventions on diarrhoea morbidity and mortality is summarised in Table 1-3. These interventions and continued feeding are described further in the text below.

Table 1-3. Summary of the evidence supporting treatment of diarrhoea with ORS and zinc

Intervention	Evidence for impact on diarrhoea
Oral rehydration therapy (use of ORS)	Appropriate use of ORS could prevent 93% of diarrhoeal deaths (Munos et al., 2010)
Zinc treatment	Reduced diarrhoea duration, severity and incidence (Lukacik et al., 2008, Haider and Bhutta, 2009, Fischer Walker and Black, 2010, Patel et al., 2010, Lamberti et al., 2013, Lazzerini and Ronfani, 2013, Liberato et al., 2015). Potential 23% reduction in mortality (Fischer Walker and Black, 2010).

Fluid replacement can prevent or reverse the symptoms of dehydration in all but the most severe cases and is the cornerstone of diarrhoea treatment (Rehydration Project, 2014). Simple mixtures of glucose and electrolytes known as ORS became available commercially in the 1970s and formed the basis of the WHO Diarrhoeal Diseases Control Programme which commenced in 1978 (WHO, 1980). The development of ORS drastically changed diarrhoea case management; before then, the only real option for fluid replacement was an intravenous drip, which was

rarely available in settings where dehydration was most common (Santosham et al., 2010). Since then, simple home treatment of acute diarrhoea has been made possible. Ongoing research and development eventually resulted in the replacement of standard ORS with more effective low-osmolarity solutions in the early 2000s (Hahn et al., 2002, WHO, 2006). It is now estimated that the appropriate use of ORS could prevent 93% of diarrhoeal deaths (Munos et al., 2010).

The therapeutic benefits of zinc have become clear more recently. On the basis of accumulated evidence, WHO and UNICEF issued a joint statement in 2004 recommending the inclusion of zinc alongside ORS in the routine management of all childhood diarrhoeal episodes (WHO/UNICEF, 2004, Fischer Walker et al., 2009). Since then, meta-analyses in a number of reviews have consistently reported that zinc given during a diarrhoeal episode can reduce diarrhoea duration, severity and incidence (Lukacik et al., 2008, Haider and Bhutta, 2009, Fischer Walker and Black, 2010, Patel et al., 2010, Lamberti et al., 2013, Lazzerini and Ronfani, 2013, Liberato et al., 2015). Less conclusive evidence supports a 23% reduction in mortality from diarrhoea (Fischer Walker and Black, 2010).

The final intervention included under the umbrella of 'diarrhoea treatment' is 'continued feeding' during episodes of diarrhoea - a nutritional intervention. Continued feeding with age-appropriate nutrition may be the best way of reducing the duration of diarrhoeal episodes (Strand et al., 2012) and improving nutrition and recovery after a diarrhoeal episode (Dugdale et al., 1982, Brown et al., 1988, Sandhu et al., 1997). However, many caregivers withhold or reduce breastmilk and food during a diarrhoeal episode (Chouraqui and Michard-Lenoir, 2007, Pantenburg et al., 2014) and continued feeding has been challenging to promote (Chouraqui and Michard-Lenoir, 2007).

It can thus be concluded that there is strong and substantial evidence in favour of the 7-Point-Plan for comprehensive diarrhoea control.

1.4.4 Barriers to effective intervention

However, despite this evidence, diarrhoea control efforts are far from optimal. Based on current levels of coverage, it is estimated that full implementation of

existing control interventions could prevent 54% of child deaths from diarrhoea by 2025. Bhutta et al suggest that 95% of child deaths from diarrhoea could be prevented if such interventions were delivered at scale and with high coverage (Bhutta et al., 2013).

However, as alluded to previously, many obstacles stand in the way of achieving this ambitious goal. Health systems often lack skilled providers, as a result of which quality of care suffers (Chopra et al., 2013). Adherence to recommended diarrhoea treatment protocols is also often poor, which is further challenged by low zinc availability and poor demand for ORS (Bhutta et al., 2010, Santosham et al., 2010). Rotavirus vaccination is yet to be rolled out in many countries and needs to be supported by development of the cold chain and health system capacity (Duclos et al., 2009). Interventions are not always optimally adapted to users' needs. The largest health gains are likely to come from accessing the hardest-to-reach individuals. However, intervention scale-up that fails to reach these individuals can increase inequities rather than reduce them (You et al., 2015).

Sufficiently resourced, innovative delivery mechanisms need to be developed to enable interventions to be delivered with high coverage (Aboud and Singla, 2012). Barriers to sanitation uptake and hygienic maintenance of latrines require fresh solutions (Cairncross et al., 2010a). Contextually relevant solutions will also need to be found to convince caregivers to change behaviours that increase the risk of diarrhoea: global prevalence of handwashing with soap after defecation is estimated at 19% (95% CI: 8%-39%) (Freeman et al., 2014) and only 34% of infants 0-5 months-of-age in low-income countries are exclusively breastfed (Bhutta and Labbok, 2011).

1.5 Epidemiology and control of childhood diarrhoea in Zambia

Below I describe the background and rationale for undertaking this research in Zambia.

1.5.1 Country profile

Zambia is a landlocked country in Southern Africa. The population is estimated at just over 16 million people and 41% of the country is urbanised (Central Statistical Office [Zambia] et al., 2014). Due to the country's historical reliance on the mining of copper ore, the urban population is concentrated in two of ten provinces: on the Copperbelt and in Lusaka, the nation's capital (Mulenga, 2003). The Zambian economy today is still vulnerable to fluctuations in copper prices, although agriculture and manufacturing industries are growing (Central Statistical Office [Zambia] et al., 2014). The Zambian economy has also been greatly affected by the HIV epidemic; HIV prevalence among adults 15-49 years-of-age is declining, but is still estimated to be 15% among women and 11% among men (Central Statistical Office [Zambia] et al., 2014). Zambia experiences high levels of both poverty and inequality; the richest 20% of the population claim 61% of the total household income and 64% of the population live below the poverty line of US$1.90 per day (UNICEF, 2016b). The proportion of the population living in poverty is three times higher in rural areas than in urban areas (Central Statistical Office [Zambia] et al., 2011).

Rural-urban disparities are also seen concerning access to water and sanitation. In 2015, only 24% of the rural population had access to an improved source of water – defined as water that is piped, obtained from a borehole, standpipe or other protected source, or rainwater (JMP) – compared with 88% of the population in urban areas. Twenty-two percent of the population in rural areas reported that they practise open defecation, compared with just 1% of the urban population (JMP, 2015).

1.5.2 Burden of childhood diarrhoea

The under-five mortality rate in Zambia was estimated at 64 deaths per 1000 live births in 2015, which translates to approximately 39,000 largely preventable child deaths over the course of the year (UN IGME, 2015). Nine percent of all child deaths in Zambia are attributed to diarrhoea and it persists as the third largest cause of mortality in this age group after pneumonia and malaria (WHO, 2015). According to the 2013-14 demographic and health survey, diarrhoea prevalence among children under-five in the two weeks preceding the survey was 16%. Children aged 6-23 months experienced the greatest burden of disease (Central Statistical Office [Zambia] et al., 2014). The true prevalence of diarrhoea is likely to be greater than these estimates suggest, as data were not collected during the peak diarrhoea season. Although morbidity does not vary by wealth status (Central Statistical Office [Zambia] et al., 2014), the consequences of severe childhood diarrhoea exert greater impact on the poor. These individuals generally have worse nutritional status (Dangour et al., 2013) and reduced access to the health service (Peters et al., 2008). Other than the psychosocial and economic costs experienced by individual families, frequent diarrhoeal episodes cost the Zambian health system approximately $26 per clinic visit and $76 per hospitalisation (Chola and Robberstad, 2009).

Many factors contribute to the burden of diarrhoea morbidity and mortality experienced by Zambia's children. The Zambian health system lacks capacity. There are nine doctors, nurses and midwives per 10,000 population, well below the WHO minimum threshold of 23 per 10,000 population (WHO, 2014). Stock-outs of essential treatments such as ORS and zinc are also frequent (Chilengi et al., 2016). As a result, zinc is so seldomly used that it is not even reported (Central Statistical Office [Zambia] et al., 2014). Although advice or treatment is reportedly sought in association with 64% of childhood diarrhoeal episodes (Central Statistical Office [Zambia] et al., 2014), caregivers seek treatment to stop diarrhoea rather than to manage diarrhoea-induced dehydration with ORS. ORS coverage in Zambia had declined (Ram et al., 2008), but appears to have increased in recent years (Central Statistical Office [Zambia] et al., 2009, Central Statistical Office [Zambia] et al., 2014). However, coupled with frequent reliance on traditional remedies (Njume and Goduka, 2012) and late presentation at clinics (Bosomprah

et al., 2016), ill children may not be treated until they are already severely dehydrated.

In addition, insufficient access to safe water and sanitation, and poor hand hygiene and suboptimal breastfeeding (environmental and behavioural risk factors for diarrhoea respectively) are leading causes of DALYs in Zambia (GBD Risk Factors Collaborators et al., 2015). Findings from other studies similarly support inadequate hand hygiene and exclusive breastfeeding practices as leading behavioural risk factors in Zambia. Although no reliable estimates are available for handwashing, estimates using data from other countries suggest that the prevalence of handwashing with soap after defecation in Sub-Saharan Africa is 14% (95% CI: 11%-18%) (Freeman et al., 2014). Proxy measures from the latest Demographic and Health Survey (Central Statistical Office [Zambia] et al., 2014) suggest that handwashing rates in Zambia are similarly low: only one in three households have soap as well as water available at the place where hands are commonly washed. Seventy-three percent of Zambian mothers report exclusively breastfeeding infants 0-5 months-of-age and the median duration of exclusive breastfeeding is estimated at 4.1 months (Central Statistical Office [Zambia] et al., 2014). However, HIV-positive mothers tend to wean their babies earlier than uninfected mothers due to fears of transmissing HIV (Omari et al., 2003). As awareness of breastfeeding messages is high (Fjeld et al., 2008), it is possible that self-reports of exclusive breastfeeding overestimate good practice (Manun'Ebo et al., 1997).

1.5.3 Programme for the Awareness and Elimination of Diarrhoea (PAED)

The burden of diarrhoea and other common infections faced by the African region is projected to grow disproportionately to other regions in coming years, if uptake of life-extending interventions continues at current rates (Liu et al., 2015). Innovative approaches to diarrhoea control are urgently needed.

In January 2012, the Centre for Infectious Disease Research in Zambia (CIDRZ), in collaboration with two government ministries (the Zambian Ministry of Health and the Ministry of Community Development, Mother and Child Health), introduced the Programme for the Awareness and Elimination of Diarrhoea (PAED) (CIDRZ,

2012). This aimed to institute comprehensive and systemic change in the approach to diarrhoea control in children under the age of five. PAED was introduced in Lusaka Province as a pilot programme and represented the first concerted effort towards diarrhoea prevention and management in Zambia. The results were intended to inform decisions concerning the expansion of diarrhoea prevention and control activities in Zambia.

Based on modelling using the 'Lives Saved Tool' (Walker et al., 2013, Fischer Walker and Walker, 2014), PAED assumed the ambitious goal of reducing childhood mortality by 15% (Bosomprah et al., 2016). Programme activities were targeted at healthcare providers and caregivers of children under-five, and centred around three areas believed to have the most potential to contribute to this goal:

1. The introduction of rotavirus vaccine through the national immunisation schedule in Zambia
2. The improvement of clinical case management of diarrhoea in government health facilities
3. Caregiver behaviour change to improve diarrhoea preventive and treatment behaviours.

Rotavirus causes severe diarrhoea and is responsible for at least a quarter of hospitalisations of children under-five with acute diarrhoea in Lusaka's main hospital (Mpabalwani et al., 1995, Steele et al., 1998). As rotavirus vaccination can reduce mortality, the introduction of the Rotarix™ vaccine was an obvious choice for the first component of PAED (Chilengi et al., 2015). The second component was addressed through the training of frontline health workers in the Integrated Management of Childhood Illnesses (IMCI). IMCI involves treating the ill child holistically rather than merely addressing the presenting illness. IMCI has been associated with improved quality of care (Bryce et al., 2005, Hoque et al., 2014), but the impact on mortality is less clear (Gera et al., 2016). The final component of the strategy involved the promotion of four preventive and treatment behaviours: exclusive breastfeeding of infants 0-5 months-of-age; handwashing with soap after toilet use; and appropriate use of ORS and zinc in the home management of diarrhoea. The potential contribution of these behaviours to reduce diarrhoea morbidity and mortality has already been described.

Figure 1-3 shows the three components of PAED and the stakeholders involved in the programme. The programme was predominantly funded by the UK charities Ark (Absolute Return for Kids Foundation) and Comic Relief. My PhD research concerned the behaviour change component of PAED, which is indicated by the logo for the London School of Hygiene and Tropical Medicine (LSHTM).

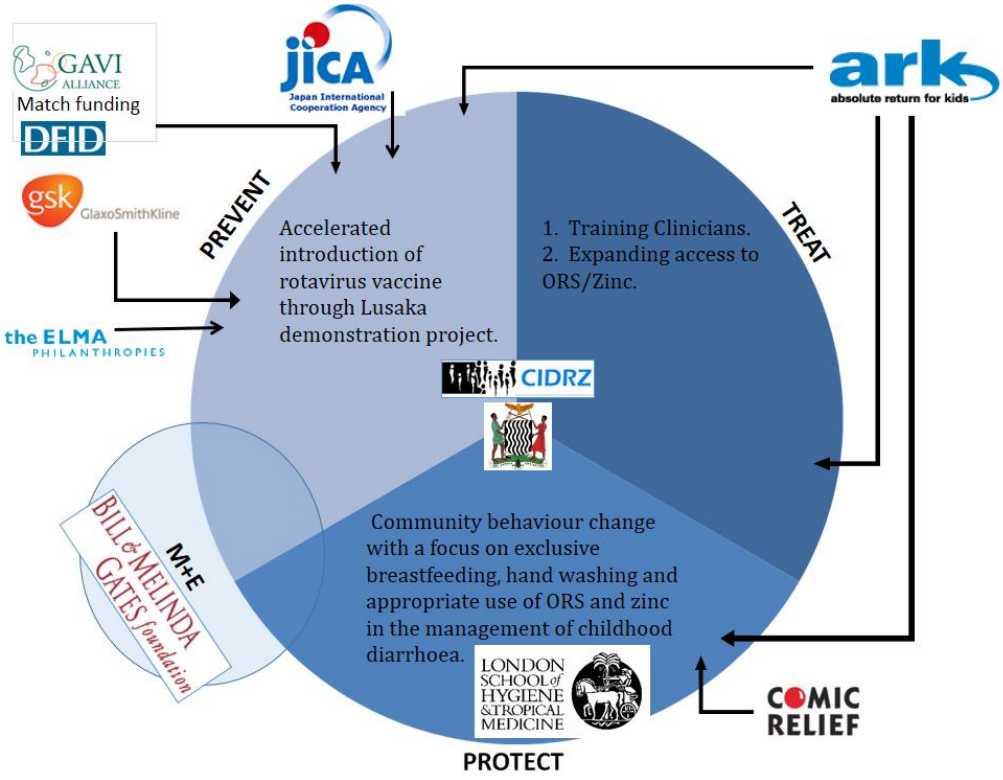

Figure 1-3. Structure of the Programme for the Awareness and Elimination of Diarrhoea, reproduced from CIDRZ Programme Documents

1.6 Origin of PhD research

In April 2013, an independent consultant carried out a midterm review of PAED to assess progress towards the programme's objectives (CIDRZ internal report). The consultant concluded that the rotavirus vaccination pilot had been successful and the scheme had strengthened the Expanded Programme on Immunisation. There was also anecdotal evidence that the IMCI training had improved quality of care in diarrhoea case management. The observations made about the behaviour change component were less encouraging; behaviour change messaging was not standardised across the programme, too many behaviours were being targeted, and there was no plan in place to measure behaviour change. The consultant concluded that the behaviour change component of PAED needed strengthening and the London School of Hygiene & Tropical Medicine (LSHTM) was engaged to provide technical assistance to improve the behaviour change arm of PAED.

The doctoral research presented in this thesis was born from practical questions concerning the design and evaluation of the behaviour change component of PAED and the ultimate goal of contributing new knowledge as to how behavioural interventions can be more effective. My thesis describes the formative research and development of a multiple behaviour change intervention to control childhood diarrhoea, and the subsequent outcome and process evaluations of this intervention. A timeline outlining when these research activites were undertaken is shown in Figure 1-4. The aims, objectives and the rationale for this research agenda are explained in more detail in Chapter 2.

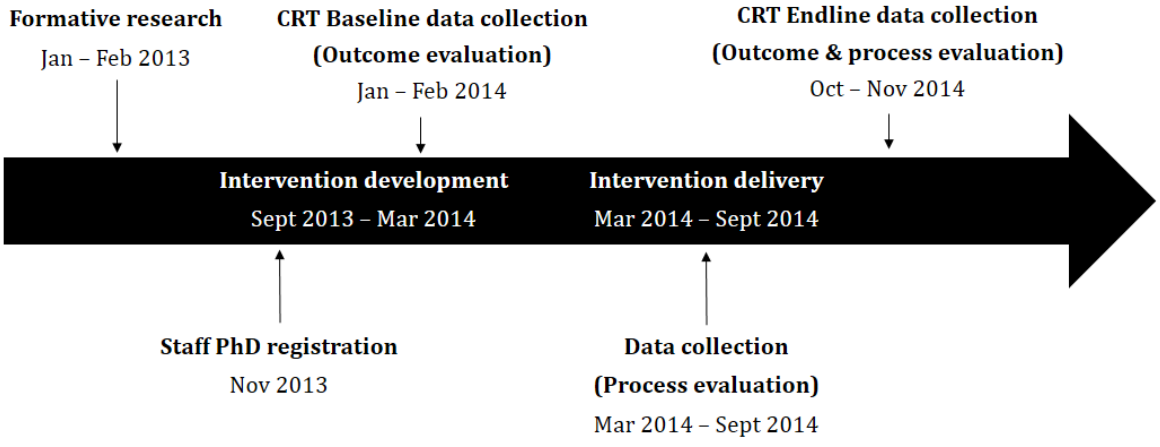

Figure 1-4. Timeline of research activities conducted

1.7 Thesis structure

This thesis comprises nine chapters divided into four sections. Research findings are presented as research papers. The composition is as follows.

Part I. Introduction and background

Part 1 sets the scene for the research. **Chapter 1** provides an overview of the epidemiology and control of diarrhoea globally and in Zambia, as well as the rationale for undertaking this work. **Chapter 2** presents the thesis' aims and objectives and a review of the relevant literature.

Part II. Intervention design

Part 2 of the thesis concerns the design and development of a theory-based, multiple behaviour change intervention. **Chapters 3 and 4** describe the formative research conducted to inform intervention development. Chapter 3 includes Research Paper 1 (Greenland et al., 2016a). **Chapter 5** describes the intervention that was developed from this formative research and presents the theory of change for the intervention.

Part III. Intervention evaluation

This third section concerns the evaluation of the intervention. **Chapter 6** describes the research methods used to evaluate the intervention. The methods presented include a Cluster-Randomised Trial (CRT) designed to measure behavioural outcomes of the intervention, and a nested process evaluation. **Chapter 7** presents the results of the outcomes evaluation (Research Paper 2 - (Greenland et al., 2016b)) and **Chapter 8** presents the results of the process evaluation and includes the manuscript for Research Paper 3.

Part IV. Discussion and implications

The thesis concludes with a fourth, final section **(Chapter 9)**, that discusses how the findings contribute to the field, reviews the limitations of the research, reflects on the implications of the research included in this thesis and proposes future research directions.

1.8 Contributions of the candidate to the thesis

I led all components of the research presented in this thesis. My research was supervised by Dr. Val Curtis at LSHTM and Dr. Roma Chilengi at CIDRZ. Funding for the research was provided by Ark (previously known as Absolute Return for Kids foundation); Comic Relief funded the intervention. The intervention was designed by a larger team, which I was part of, but did not lead. CIDRZ oversaw the implementation of the intervention. My colleague Jenala Chipungu played an integral role in all aspects of the research and implementation of our programme.

The research elements of the project comprised formative research, and outcomes and process evaluations. I conceived and developed all research protocols and tools, and led data collection, analysis and report writing. Between January 2013 and November 2014, I worked in close collaboration with CIDRZ, spending large periods of time at CIDRZ's campus in Lusaka. I am the first author on all three papers included in this thesis. Two of these papers have been published in peer-reviewed journals (Greenland et al., 2016a, Greenland et al., 2016b) and one is included as a manuscript prepared for publication. Each paper is preceded by a cover sheet which details the role I played in the work.

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Chapter 2: Complex behaviour change interventions

2.1 Overview of chapter

The ultimate goal of this research is to contribute to improving the effectiveness of multiple behaviour change interventions for diarrhoea control. This chapter sets out the rationale for this programme of work and concludes with the thesis aims and objectives. To achieve the thesis aims, I outline the ineffectiveness of current behaviour change interventions targeting handwashing with soap, exclusive breastfeeding, and appropriate use of ORS and zinc. I then present the rationale for testing a novel, theory-based, multiple behaviour change intervention and consider how developments in methodologies for complex interventions can be used to strengthen the design and evaluation of new interventions. Finally, I introduce a conceptual framework to guide the development of a theory-based intervention. I outline how an integrative outcome and process evaluation based on the intervention's theory of change, can improve the ability to contribute to the development of better-designed, more effective interventions.

2.2 Behaviour change interventions for diarrhoea control

2.2.1 Effectiveness of current interventions

All of the diarrhoea control strategies reviewed in Chapter 1 involve some level of caregiver engagement with a particular behaviour or set of practices that reduce either the risk of diarrhoea or its consequences. However, as we have also seen, there is a discrepancy between recommended practice and actual practice, both in Zambia and globally. Behaviour change interventions delivered via mass media, or to groups or individuals in clinics or communities rarely include appropriate behaviour change techniques and thus often fail to improve caregiver compliance with healthy behaviours (Michie et al., 2008). The extent of this failure is described below in relation to the four behaviours targeted by PAED: handwashing with

soap; exclusive breastfeeding; and appropriate use of ORS in the home management of childhood diarrhoea; and similarly the employment of zinc.

Most early trials of handwashing with soap interventions with diarrhoea outcomes neglected to collect information on handwashing compliance (Luby, 2001, Curtis and Cairncross, 2003), limiting the ability to draw conclusions about the success of these programmes. Accumulated evidence from later handwashing interventions with behavioural outcomes suggests that large handwashing interventions are rarely successful (Huda et al., 2012, Briceno et al., 2015). Some small, intensive programmes have achieved modest improvements in behaviour on some but not all promoted handwashing occasions (Stanton and Clemens, 1987, Luby et al., 2006, Langford et al., 2011, Biran et al., 2014, Contzen et al., 2015). When behaviour change is achieved, initial improvements are rarely being sustained over time (Waddington et al., 2009, Vindigni et al., 2011). There are two notable exceptions (Cairncross et al., 2005, Bowen et al., 2013). However, these interventions involved high levels of prolonged, intensive contact with the target population, which is unlikely to be feasible or scalable in standard programmatic settings.

Interventions aiming to increase the duration of exclusive breastfeeding typically involve education or counselling provided by lay (including peer) or professional counsellors. A recent systematic review examined the effectiveness of community and facility-based interventions on exclusive breastfeeding among infants 1-5 months-of-age (Haroon et al., 2013). The review included the findings from 29 randomised controlled and quasi-experimental trials conducted in low-income countries: 21 of the studies were associated with a significant increase in the duration of exclusive breastfeeding following intervention. However, there was considerable variation in the effect sizes observed amongst the successful interventions. This is not surprising in a review of studies of different interventions conducted in different populations and settings. However, it limits the ability to draw conclusions about the replicability or scalability of current approaches. The most promising interventions used peer counsellors and involved a combination of facility and community interventions (Bhutta et al., 2008, Tylleskar et al., 2011, Jolly et al., 2012, Haroon et al., 2013, Sinha et al., 2015,

Rollins et al., 2016). However, further research is needed to identify how best to combine and scale-up these approaches (Bhutta and Labbok, 2011).

Comparatively few studies have evaluated the effectiveness of interventions to promote ORS use within the home. The authors of a recent systematic review identified only 19 such studies between 1970 and 2012 (Lenters et al., 2013). The studies tested interventions ranging from mass media and social marketing to individual or group counselling communication strategies. The review concluded that the effectiveness of current approaches to ORS behaviour change is poor (Lenters et al., 2013). There was one key exception: interventions involving the co-promotion of ORS and zinc significantly increased the likelihood of a mother treating a diarrhoeal episode with ORS (relative risk: 1.82; 95% CI 1.17 - 2.85) (Lenters et al., 2013). The two large community-based effectiveness trials included in this meta-analysis compared standard treatment (ORS prescription) with enhanced treatment involving zinc education and prescription as well as ORS (Baqui et al., 2004, Bhandari et al., 2008). It was suggested that uptake of ORS was driven by increased satisfaction with diarrhoea treatment, as zinc treatment can stop diarrhoea, whereas ORS cannot. Increased uptake of ORS was therefore an unintended, positive consequence of zinc introduction.

2.2.2 Developments in behaviour change theory and practice

Theory about behaviour change has evolved considerably in recent decades, but practice has been slow to follow. Diarrhoea control in the early years of the WHO Programme for the Control of Diarrhoeal Disease centred largely on increasing the global production of ORS and training health workers on oral rehydration therapy (Feachem et al., 1983, Forsberg et al., 2007). These efforts resulted in drastic increases in the availability of oral rehydration therapy during the 1980s (Claeson and Merson, 1990, Victora et al., 2000). However, increased availability (and awareness) of ORS did not translate into comparable increases in ORS usage, which has stagnated and even declined in many place since the 1990s (Enzley and Barros, 1997, Ram et al., 2008). The first diarrhoea control strategy was based on two misconceptions: the belief that uptake of interventions involving products is achieved by increasing the availability of the product; and the premise that people will adopt healthy behaviours, or discontinue behaviours that increase the risk of

ill-health, if they are provided with information that increases their awareness of the health risks associated with their current behaviour.

Numerous authors have since shown that health education approaches that focus solely on enhancing knowledge about health risks rarely change behaviour (Loevinsohn, 1990, Albarracín et al., 2005, Coulter and Ellins, 2007, Kelly and Barker, 2016). There is undoubtedly some need to increase knowledge about the target behaviours, for instance how to initiate breastfeeding, or how to prepare ORS solution. However, other drivers of behaviour are likely to be far more important (Michie et al., 2008). Over time, increased recognition of the importance of the political, social, environmental and economic determinants of health-related behaviour has resulted in a shift in thinking from education-based programmes to more holistic health promotion (Kirby et al., 2007, Glanz et al., 2008, Noar, 2008, Aboud and Singla, 2012, Xiao et al., 2012). Nevertheless, education-based interventions are still commonplace. For example, 12 of 26 handwashing interventions included in a recent systematic review involved education about germ theory and handwashing technique (Freeman et al., 2014).

With diarrhoea still an avoidable cause of lost DALYs (Fischer Walker et al., 2013, GBD Risk Factors Collaborators et al., 2015), the implementation of effective interventions to encourage people to adopt improved diarrhoea management and preventive behaviours is just as important as ever, particularly if ambitious goals for diarrhoea control are to be met (WHO/UNICEF, 2013, United Nations, 2015). The lack of effective, scalable approaches hinders progress and suggests that we need to change the way we design interventions. To improve intervention effectiveness, we need to develop innovative approaches and ensure that they reflect advances in understanding about the drivers of behaviour.

2.3 Multiple behaviour change

2.3.1 Background to multiple behaviour change

Behaviour change interventions generally target single behaviours, but multiple behaviours need to change to prevent diarrhoea and reduce its consequences. One way to innovate could be to target multiple behaviours at the same time.

Although interventions to change multiple behaviours have existed for some time, the explicit study of multiple behaviour change is relatively new. Little is known about how the number, type and sequence of behaviours addressed might influence behavioural outcomes and health impact. Proponents of multiple behaviour change interventions argue that reducing several risk factors simultaneously can be more effective in controlling public health problems with multiple causes or multiple transmission routes (Prochaska and Sallis, 2004, Eisenberg et al., 2007, Prochaska et al., 2008, Sweet and Fortier, 2010, Spring et al., 2012). This rationale is based largely on knowledge that risk practices often cluster at the individual-level (Marmot, 2006, Marmot et al., 2008). For example, combined diet and exercise interventions may be more successful at achieving weight loss than single interventions (Sweet and Fortier, 2010, Waters et al., 2011).

As the agents of gastroenteric infections use multiple routes to reach new hosts, it is plausible that WASH interventions targeting multiple risk factors could also have an additive impact on diarrhoea prevention. However, whilst WASH interventions often target more than one behaviour, few good quality trials have tested combinations of interventions, so there is limited evidence to support this hypothesis (Fewtrell et al., 2005, Waddington et al., 2009). Comprehensive multiple behaviour change interventions for diarrhoea control are scarce. If it is possible to change multiple behaviours through a single intervention, exploration of an intervention that combines diarrhoea preventive and therapeutic interventions would be beneficial.

2.3.2 Determinants of the target behaviours and their implications

Unlike lifestyle interventions such as diet and exercise, the four behaviours targeted in Zambia are linked by their role in diarrhoea control but are otherwise quite different. Handwashing with soap is an everyday, habitual behaviour; exclusive breastfeeding occurs for a temporary period at a particular life stage; and both ORS and zinc need to be used each time that a child has diarrhoea. These behaviours are all influenced to some extent by socio-demographic factors that are hard to change, while breastfeeding is also affected by important biological factors, such as insufficient milk, sores on nipples (Thulier and Mercer, 2009), or maternal

HIV status (Doherty et al., 2012). The similarities and differences in other important determinants of these behaviours are discussed below.

Habitual behaviours such as handwashing are difficult to change, because they proceed automatically in a stable context in response to direct cues (Neal et al., 2006) and, therefore, past habits are more predictive of future behaviour than intentions (Webb and Sheeran, 2006). Even given positive intentions to wash hands with soap, the absence of physical reminders to handwash may also limit a person's ability to develop a new handwashing habit (Neal et al., 2015). The physical environment is therefore an important determinant of handwashing behaviour. The presence or absence of water, soap and handwashing infrastructure in a convenient place can significantly affect handwashing rates (Curtis et al., 2009, Luby et al., 2009, Aunger et al., 2010, Dreibelbis et al., 2013, Hulland et al., 2013). The other behaviours may also have a habitual component, but they occur less frequently than handwashing. Exclusive breastfeeding does not require physical infrastructure or products, although returning to work often represents a structural barrier to breastfeeding (Thulier and Mercer, 2009). As with handwashing, diarrhoea treatment also requires products to be available and affordable, and this can influence ORS and zinc use (Winch et al., 2008).

All four behaviours are influenced by social norms, which serve to maintain existing patterns of behaviour (Briscoe and Aboud, 2012, Bicchieri, 2014). Social influences are particularly important drivers of infant feeding and diarrhoea treatment choices. For instance, the level of social and familial support a woman receives affects breastfeeding initiation and exclusive breastfeeding duration (Meedya et al., 2010, Dennis et al., 2012, Doherty et al., 2012, Johnson et al., 2012, Upadhyay et al., 2012). The knowledge and credibility of healthcare providers also forms part of this sphere of social influence (WHO, 2010, Laantera et al., 2011, Eamer and Randall, 2012). Past experience with diarrhoea and the actions of healthcare providers similarly influence caregivers' opinions on available options for diarrhoea treatment (Santosham et al., 2010, SHOPS Project, 2011).

All four behaviours are also frequently undervalued by caregivers: handwashing with soap can be seen as irrelevant compared with bigger life struggles (Langford and Panter-Brick, 2013); exclusive breastfeeding competes with attractive alternatives such as formula milk (Loughlin et al., 1985, Rollins et al., 2016); and

ORS and zinc compete with popular, perceivably more potent, and often injectable anti-diarrhoeals (Winch and Fitzgerald, 2004). This means that any intervention has the challenge of overcoming competing priorities.

The value attached to performing a behaviour can outweigh the costs when there is sufficient motivation to achieve a goal. Sub-conscious motives may have evolved to enable our ancestors to perform functions that aid survival or reproduction (Aunger and Curtis, 2013, Aunger and Curtis, 2015). For example, the motive *disgust* is considered to be an adaptive response that protects us from disease by encouraging the avoidance of, among other things, ill people and contaminated environments (Curtis and Biran, 2001, Curtis et al., 2004, Oaten et al., 2009). *Disgust* has been shown to be an important determinant of handwashing when hands are visibly dirty (Curtis and Biran, 2001, Aunger et al., 2010). *Disgust* messaging has consequently been used experimentally (Judah et al., 2009) and in campaigns to drive uptake of handwashing with soap (Scott et al., 2008, Biran et al., 2014). Enhancing other motivations such as *affiliation* (desire to conform and belong) and *nurture* (desire to care for children) (Curtis et al., 2009, Aunger et al., 2010) can positively influence handwashing. As *affiliation* applies broadly to human behaviour and *nurture* applies broadly to childcare, it is plausible that these motives could also be manipulated to enhance other desired behaviours, such as exclusive breastfeeding and diarrhoea treatment with ORS and zinc.

Although there are some important differences between the target behaviours, they are also influenced by a number of cross-cutting determinants. This suggests that it could be feasible to develop a multiple behaviour change intervention targeting these behaviours.

2.4 Improving the effectiveness of complex interventions

2.4.1 Complex intervention research

A diarrhoea control intervention that targets multiple, different behaviours and measures multiple outcomes mediated by different factors is a 'complex intervention' (Campbell et al., 2000). The UK Medical Research Council (MRC) has published a number of guidance documents for the development and evaluation of

complex interventions (Campbell et al., 2000, Craig et al., 2008, Moore et al., 2015a). These documents, which summarise the latest developments in complex intervention research, have had an important influence on practice in many sectors (Craig and Petticrew, 2013). Complexity complicates intervention design and makes it more difficult to model how an intervention may bring about change. Complexity also makes it harder to identify which elements of an intervention are important in bringing about change, which makes it challenging to build knowledge on the most effective intervention approaches.

Even in 1992, Stanton and colleagues proposed that behavioural interventions for the control of diarrhoeal diseases should follow a 'theory-driven' approach (Stanton et al., 1992). This recommendation is in line with the current MRC guidelines (Craig et al., 2008) and a growing body of evidence suggesting that interventions grounded in theory are often more successful (Painter et al., 2008, Glanz and Bishop, 2010). Theories of behaviour and behaviour change provide us with hypotheses about how drivers of behaviour can be influenced by an intervention (Michie et al., 2008, Glanz and Bishop, 2010, Head and Noar, 2014). It is therefore intuitive that their appropriate use should contribute to greater success. However, behaviour theories are not automatically useful: some authors have argued that popular theories – the Theory of Planned Behaviour and the Transtheoretical Model – are substantially flawed (West, 2005, Sniehotta et al., 2014). Furthermore, despite general scientific consensus on the importance of theory in intervention design, interventions are more often 'theory-inspired' than they are 'theory-based' (Painter et al., 2008, Michie et al., 2016).

Theory can be 'used' to inform an intervention without necessarily being applied. An intervention becomes theory-based when theoretical constructs, hypothesised to be important determinants of behaviour, are used to select the 'behaviour change techniques' employed to change it (Michie et al., 2008). These behaviour change techniques are the 'active ingredients' of an intervention that specify how the intervention should lead to behaviour change. The fact that many interventions that purport to be theory-based do not seek to modify specific theoretical constructs may well explain why Prestwich and colleagues concluded that theory-based interventions are no more effective than interventions with no theoretical grounding (Prestwich et al., 2014). Lack of appropriate theory use at the design

stage limits the potential effectiveness of an intervention and in turn limits the evaluation questions that can be answered.

2.4.2 Theory-based evaluation

Evaluation should provide information to improve interventions and policy decisions (Weiss, 1998). Impact and outcome evaluations address critical cause-effect questions and provide a measure of the magnitude of intervention success, but they cannot tell us why an intervention has resulted in the measured outcomes. Theory-driven evaluation approaches offer a way of improving the effectiveness of behaviour change interventions by providing a systematic way of answering these 'how and why' questions. Broadly speaking, theory-driven evaluation can be defined as the use of *"…an explicit theory or model of how the program causes the intended or observed outcomes and an evaluation that is at least partly guided by this model"* (Rogers, 2000).

The approach emerged as a way of improving learning from an evaluation, born from frustrations with existing 'black box' evaluations and their limited capacity to explain evaluation findings and influence policy (Pawson and Tilley, 1997, Weiss, 1998). Theory-driven evaluation approaches have evolved considerably since their first introduction (Chen, 1990, Chen et al., 1992, Weiss, 1995, Pawson and Tilley, 1997, Weiss, 1997). The two main approaches, 'theory-based evaluation' (Weiss, 1995) and 'realistic evaluation' (Pawson and Tilley, 1997), both aim to answer questions about causality, but they have fundamentally different ideas about the role of theory in a theory-driven evaluation (Stame, 2004).

Theory-based evaluation, often simply referred to as 'theory of change', is based on the premise that interventions all have *"a theory of how and why an initiative works"* (Weiss, 1995), even if the theory of change has not been explicitly stated. Weiss therefore proposes that this theory forms the basis for evaluation. A theory of change model is created to depict all of the intervention activities and the pathways through which the intervention may lead to change. These pathways can be tested to assess the intervention's mechanism of change. The approach was initially developed as an evaluation tool for complex community interventions

(Weiss, 1995, Fulbright-Anderson et al., 1998) and has been particularly popular in international development (Vogel, 2012).

The realistic evaluation approach was developed by Pawson and Tilley at around the same time as theory-based evaluation. It was intended to offer an alternative to randomised trial-based evaluation (Pawson and Tilley, 1997), although the wisdom of avoiding randomisation has been contested (Bonell et al., 2012). Realistic evaluations investigate a number of plausible mechanisms through which an outcome might be achieved in different contexts, based on the premise that the programme does not bring about change, but the people exposed to it in a given context act in a way that leads to change. Realistic evaluation seeks to uncover evidence to support tested 'Context-Mechanism-Outcome' (CMO) configurations, and thereby predict the conditions needed for an intervention to work in another setting. Realistic evaluation may thus be better suited to simpler interventions where a detailed understanding of the mechanisms at play can be achieved (Blamey and Mackenzie, 2007).

Regardless of the differences between the main approaches, theory-driven evaluation should always involve formation of a 'programme theory' and subsequent use of this theory to guide evaluation questions, evaluation design, measurement of programme theory constructs and description and explanation of causal associations (Coryn et al., 2011). Good programme theory specifies what an intervention plans to do and describes how these actions are hypothesised to lead to change. Different authors call these two components of programme theory a number of different things (Chen, 1990, Weiss, 1995, Pawson and Tilley, 1997, Donaldson, 2012, Moore et al., 2015a) (see Figure 2-1). The terms are confused and inconsistently used in the literature (Coryn et al., 2011). Carol Weiss's terminology (Weiss, 1995) is the most intuitive, hence I will hereafter use the terms 'theory of change' to describe the entire programme theory model, 'implementation theory' to describe what the intervention plans to do and 'programme theory' to describe how the intervention is hypothesised to produce change.

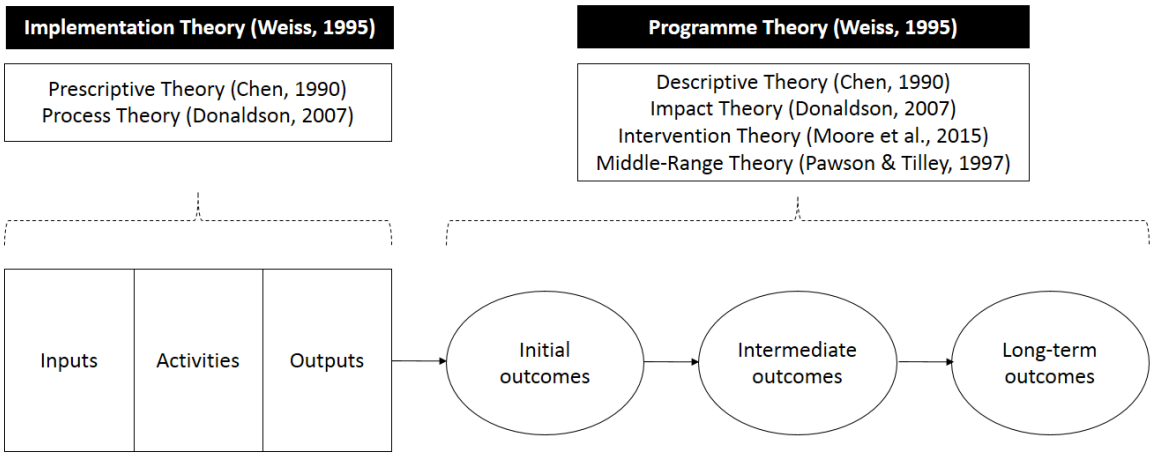

Figure 2-1. A simple theory of change model showing common terminology, modified from (Coryn et al., 2011)

Figure 2-1 illustrates the connection between implementation and programme theory in a simple, linear theory of change model. In reality, these theories are – and should be - much more complex than this (Stame, 2004). For example, more sophisticated, 'ecological' programme theory models consider how contextual factors might influence intervention uptake and outcomes (Chen, 2005). However they are depicted, a theory of change model should provide a clear description of the hypothesised links between activities, outputs and outcomes, and identify contextual factors influencing these processes (Weiss, 1995). However, programme theory models describing how an intervention intends to bring about change are rarely reported by investigators (Michie and Abraham, 2004, Chandler et al., 2016). The theory of change approach offers a way of improving both the intervention design and evaluation elements of the MRC framework for complex interventions (De Silva et al., 2014). In the evaluation stage, theory of change removes the distinction between outcome and 'process' evaluation, thus strengthening the ability to draw conclusions about the intervention, its effectiveness and how change has been brought about (De Silva et al., 2014).

A process evaluation is *"a study which aims to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors"* (Moore et al., 2015b). As many evaluation findings are inconclusive, process evaluations can strengthen claims of causal attribution, especially when they are integrated into outcome evaluations (Oakley et al., 2006, Craig et al.,

2013). Process evaluations also guide decision-making about the future of an intervention by helping to ascertain whether intervention outcomes are attributed to the intervention content or the way in which the intervention has been delivered (Oakley et al., 2006). Process evaluation is therefore essentially a variant of theory-driven evaluation. Examining how the intervention content influences intervention outcomes represents a test of programme theory, while studying intervention delivery is a test of implementation theory. Assessing both programme theory and implementation theory is important, because these different causes of intervention failure can have major policy implications, as illustrated in Figure 2-2.

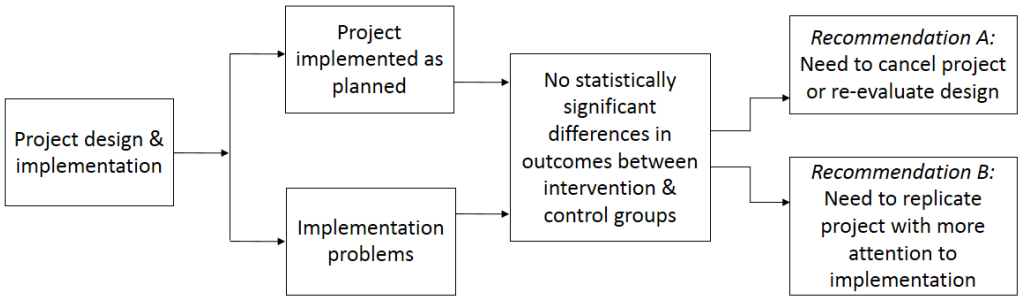

Figure 2-2. Implications of different causes of intervention failure on policy decisions, modified from (Bamberger et al., March 2010)

Despite the importance of integrative process evaluations that test the entire theory of change, evaluators in the past have focussed primarily on the measurement of implementation theory, i.e. whether an intervention is delivered as intended (Rogers and Weiss, 2007). Recent guidance on process evaluation of complex interventions (Moore et al., 2015b) partially meets calls for increased testing of intervention causal processes (Grant et al., 2013). However, there is an acute lack of published studies demonstrating how recommended methods have been employed in process evaluations (Van Belle et al., 2010). This shortage of examples constrains application of the principles in the guidelines to the evaluation of real interventions.

In summary, complex interventions bring challenges for both design and evaluation. Interventions that are grounded in theory are often more successful, but theory is rarely applied appropriately during the design phase or reported on by way of an intervention theory of change model. In a complex intervention it can

be more difficult to understand how and why an intervention has produced its measured effects and even more important to attempt to do so. Integrative theory-based outcome and process evaluation can help support claims about intervention outcomes and contribute to the evidence-base about what works. This ultimately contributes to the development of better-designed, more effective interventions.

2.5 Conceptual framework

2.5.1 Evo-Eco theory of behaviour

It is useful to follow a conceptual framework to guide the design and evaluation of a complex intervention. The multiple behaviour change intervention developed in Zambia was grounded in the 'Evo-Eco' theory of behaviour from the recently-published 'Behaviour Centred Design' approach developed at LSHTM (Aunger and Curtis, 2016). The outcome and process evaluation of the resulting intervention followed an evaluation framework based on the intervention's theory of change (described above). The Evo-Eco theory and the Behaviour Centred Design approach are described here.

A plethora of different theories is used in public health in an attempt to explain and change behaviour (Davis et al., 2015). Most theories concentrate on understanding and influencing behaviour at the intrapersonal, usually cognitive, level (Noar and Zimmerman, 2005), often using different terminology to describe similar constructs. There is a lack of guidance on which theory to use in a given context (Michie, 2008). However, there are some recommended ways forward. Existing theories have been criticised for failing to consider the influences of interpersonal (social, cultural), organisational, community, policy and environmental variables on behaviour (Glanz and Bishop, 2010). Ecological models could provide a way forward, because they consider how behaviour is influenced by multiple factors acting and interacting at multiple levels, usually including sociocultural, environmental and individual factors (Sallis et al., 2008).

Ecological approaches are not new (McLeroy et al., 1988), but their popularity has increased because they can be used to develop complex interventions that target determinants of behaviour at multiple levels. As behaviour change requires inputs

to modify factors in the physical and social environment, as well as in the individual person, public health interventions that follow ecological models and seek to change both people and the environment are thought to have the most potential for success (Sallis et al., 2008). Ecological models vary in content and scope: some are models of behaviour (Lewin and Cartwright, 1951, Barker, 1968, Bronfenbrenner, 1979), while others provide a way of developing interventions (McLeroy et al., 1988, Stokols et al., 2003).

The intervention developed in Zambia followed the Evo-Eco theory of behaviour (Aunger and Curtis, 2014), a generic ecological model for health behaviour. The model considers how factors acting at multiple levels in the physical, social and biological environment influence psychological factors in the brain (automated / habitual, motivated and rationalised) and the physical body. These factors in turn determine behaviour in a given behaviour setting (the social and physical situations in which a behaviour takes place). This model was selected over other ecological models because it recognises important developments in the understanding of motives (Aunger and Curtis, 2013) and habit formation (Neal et al., 2006), and considers the influence of behavioural settings, first developed in an earlier ecological model (Barker, 1968).

2.5.2 Behaviour Centred Design

A further advantage of Evo-Eco is that it forms the theory behind a larger framework comprising a five-step process for the design of behaviour change interventions known as the Behaviour Centred Design Approach (Aunger and Curtis, 2016). Figure 2-3 depicts these five steps (Assess, Build, Create, Deliver, Evaluate) and the Evo-Eco theory of behaviour, which is central to the framework.

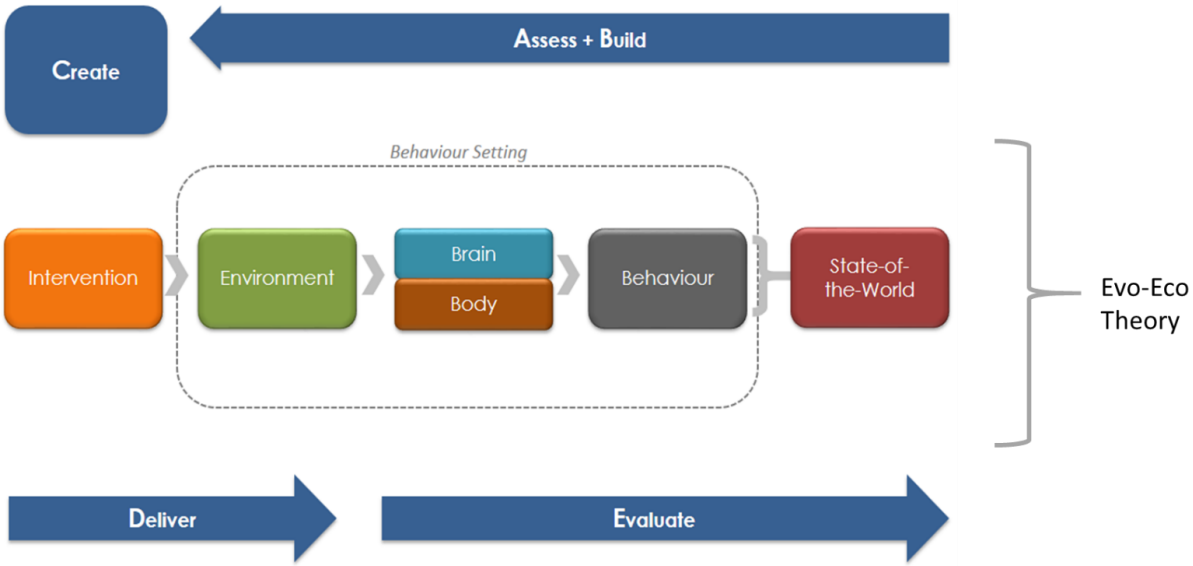

Figure 2-3. The Behaviour Centred Design Approach, modified from (Aunger and Curtis, 2016)

The first step, **A**ssess, involves reviewing what is already known and unknown about the behavioural problem in the intervention context according to the behavioural determinants of the Evo-Eco model. This information is brought together in a 'framing workshop' attended by key stakeholders to align expectations about the intervention and identify gaps in knowledge about the target behaviour(s). The second step focuses on **B**uilding on the information gathered in the assess phase. This usually involves formative research to learn more about local practice of behaviours of interest and to identify and test hypotheses about contextually-important determinants of these behaviours. The third step **C**reate, is the stage where insights from the formative research are used to design a behaviour change intervention. This step is iterative, and involves cycles of concept testing and revision, often led by a professional creative agency. The fourth and fifth steps in the framework concern the **D**elivery and **E**valuation of the intervention that has been developed. The importance of evaluating intervention implementation and mechanisms of change as well as intervention outcomes, is specified in the Behaviour Centred Design approach (Aunger and Curtis, 2016).

The view that an evaluation should follow an intervention's theory of change is in keeping with the theory of change approach to intervention design and evaluation

developed by De Silva and colleagues (De Silva et al., 2014). The intervention design steps are better defined in the Behaviour Centred Design approach based on Evo-Eco theory, but the evaluation step is developed in greater detail in the theory of change approach. Used in combination, these two frameworks can strengthen the design and evaluation of complex behaviour change interventions.

2.5.3 Formative research

Formative research, also known as 'formative evaluation' (Atkin and Freimuth, 1989, Glasgow and Linnan, 2008b), is the term used to describe research conducted to inform the development of contextually-appropriate behaviour change interventions. Formative research plays an important role in the development of an intervention based on the Behaviour Centred Design approach.

In addition to drawing on behaviour theory and previous experience, Aboud and Singla highlight the importance of understanding the target audience in their thought-provoking paper on the challenges associated with changing health behaviours in low-income countries:

> *"Strategies forming the basis of interventions and programs to change behaviour need to focus on three sources: theories of behaviour change, evidence for the success and failure of past attempts, and an in-depth understanding of one's audience." (Aboud and Singla, 2012)*

Formative research provides a way of studying behaviour in context and improving understanding about the target audience. Formative research was originally developed to inform social marketing and communication campaigns (Palmer, 1981, Atkin and Freimuth, 2012). In public health, formative research has come to be regarded as an important contributor to intervention success (Higgins et al., 1996, Curtis et al., 1997, Merzel and D'Afflitti, 2003, Randolph and Viswanath, 2004, Noar, 2006). As a result, it is increasingly recognised to be an essential aspect of the intervention design process (Glasgow and Linnan, 2008a, Chandler et al., 2016). When conducted well, formative research improves understanding of the factors promoting and inhibiting uptake of a target behaviour(s) in the target population, which enables intervention content to be tailored to reflect local conditions and needs.

2.6 Problem addressed by this thesis

Pertinent points from the literature reviewed in this chapter are summarised here to recount the problem addressed by this thesis.

A large part of the success of diarrhoea control strategies hinges on the ability of behaviour change interventions to encourage caregiver uptake of improved diarrhoea management and preventive behaviours. However, existing behaviour change interventions to control diarrhoea have achieved mixed success. Novel approaches based on the newest theoretical advances need to be developed and tested. One such novel approach involves targeting behaviours together instead of separately. However, this makes an intervention inherently 'complex', which brings challenges for intervention design and evaluation.

Interventions grounded in theory are generally thought to be more likely to be successful. However, theory is often not used properly to develop interventions and, when it is used, a theory of change model illustrating how the intervention proposes to bring about change is rarely developed. Evaluations of complex interventions are also criticised for failing to conduct theory-based, integrative outcome and process evaluations to establish how and why an intervention has succeeded or failed. This limits the ability to build learning on effective intervention approaches.

Theory-based approaches to intervention design and evaluation offer a systematic way of considering how an intervention should produce change and of investigating how and why an intervention has succeeded or failed. Ecological models of behaviour consider determinants of behaviour at multiple levels and, when combined with formative research, can lead to the creation of comprehensive interventions that are tailored to the target audience. Ensuring that theory is at the heart of both intervention design and evaluation can be aided by use of a conceptual framework based on the Behaviour Centred Design approach and the intervention's theory of change.

2.7 Thesis aims and objectives

2.7.1 Aim

The aim of this PhD research is to develop and rigorously evaluate whether and how a novel multiple behaviour change intervention can improve caregiver practice of four behaviours associated with diarrhoea prevention and management. A further aim is to contribute to the improved design and effectiveness of behavioural interventions to control diarrhoeal diseases.

2.7.2 Objectives

1. Conduct formative research to inform the design of a theory-based multiple behaviour change intervention to improve the control of diarrhoeal diseases in Lusaka Province, Zambia.

2. Evaluate, using a cluster-randomised trial design, whether a novel behaviour change intervention can improve caregiver practice of exclusive breastfeeding, handwashing with soap, preparation and use of ORS and zinc treatment.

3. Conduct process evaluation to explore how i) intervention content and ii) intervention delivery influence caregiver uptake of the target behaviours.

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PART II

Intervention development

Chapter 3: Formative research on ORS & zinc

3.1 Overview of chapter

Formative research was conducted to inform intervention development. The formative research involved a number of different methods to explore the four behaviours and their determinants, which resulted in the generation of a large amount of rich data. For ease of reporting and to do justice to the findings, the formative research has been split into two parts. This chapter reports the formative research on ORS and zinc use as a published paper (Research Paper 1) (Greenland et al., 2016). Chapter 4 covers the unpublished formative research conducted on handwashing with soap and exclusive breastfeeding. This chapter first introduces the research questions, study setting and methods used in this research.

3.2 Framing the research questions

To stand a better chance of developing an intervention that would promote uptake of healthy behaviours, we needed to ensure that our formative research would uncover factors affecting uptake of the target behaviours in our target population. If interventions that are grounded in theory are more likely to be successful (see Chapter 2), and formative research findings inform intervention design, it follows that formative research should also be theory-based.

Following the Behaviour Centred Design approach to formative research (Aunger and Curtis, 2016), we held a two-day inception workshop in November 2012 to review the Research Protocol and identify knowledge gaps. The workshop built on knowledge of the literature on the target behaviours and their determinants and the practical experience of Zambian and British researchers attending the workshop. The result was a set of hypotheses and questions that the research would need to answer.

Information about the target behaviours discussed during the framing workshop is summarised in Table 3-1 and is discussed in the text below.

Table 3-1. Summary of existing knowledge of the target behaviours and research needs discussed during the formative research inception workshop

(Exclusive) Breastfeeding of infants 0-5 months-of-age	**Handwashing with Soap at key times (to be determined) at a convenient place**	**ORS and zinc preferentially selected and correctly used to manage childhood diarrhoea**
Research questions: What is the current practice and when, where, involving whom, with what, and how does it take place? How does behaviour differ across different settings? What exceptions are there? **Purpose:** Define the precise behaviour change task(s) and target audience(s).		
Know: reported behaviour (from Demographic and Health survey data (PAHO/WHO, 2003), focus groups conducted by CIDRZ and other existing studies (cited below)); HIV status affects breastfeeding practices (Omari et al., 2003) and distance from health facilities affects care-seeking behaviour. **Don't know:** actual (observed) behaviour or detail about practices in peri-urban and rural settings; real attendance at clinics when a child has diarrhoea.		
Research questions: How do factors specified in the Evo-Eco theory of behaviour influence current practices and inhibit uptake of the target behaviours? **Purpose:** Identify why people do what they do and how future behaviour could be encouraged**.**		
Know: practice is affected by i) HIV status (and conflicting messages on avoiding vertical transmission (WHO, 2010, PAHO/WHO, 2003); ii) returning to work after 3 months (women in formal employment); iii) desire to increase weight of baby; poverty (breastfeeding seen as the choice for the poor). **Don't know:** who influences whom or the role of the determinants of behaviour from the Evo-Eco perspective (most research in Zambia conducted among HIV-positive mothers (Chisenga et al., 2005, Chisenga et al., 2011, Fjeld et al., 2008)).	**Know:** a reasonable amount about handwashing determinants from other studies (Aunger et al., 2010, Curtis et al., 2009). **Don't know:** water and soap availability and cost, proximity of toilets to homes; whether determinants of behaviour found elsewhere hold in these settings.	**Know:** proximity to clinics and beliefs about efficacy of diarrhoea treatment options both affect caregiver choices (CIDRZ, unpublished). **Don't know:** how diarrhoea cases are managed in these communities; levels of awareness and beliefs about different treatment options held by different actors; proximity of homes to clinics/kiosks where ORS and zinc are available and purchasing practices; knowledge on correct use of ORS and zinc.
Research question: How do people communicate? Where is influence being exerted, what is discussed? **Purpose:** To identify channels that can be used to reach the target audience.		
Know: interactions take place that are health related: clinic, pharmacy, community outreach points and other health visits; social (including festivals and celebrations); and practical (e.g. while shopping, trading). **Don't know:** details about these interactions and the influence exerted, media consumption / exposure; or exposure to other programmes targeting these behaviours and how this might affect our programme.		

We established that knowledge about practice of the target behaviours in the target population was limited to reported behaviour from household surveys, a few studies and anecdotal information from programmatic work. We discovered that we knew very little about actual practices in the target population, or how they varied in peri-urban and rural areas. Although we had some knowledge on likely determinants of behaviour from other studies, there were many gaps that

needed to be addressed by the formative research. Little was known about the determinants of exclusive breastfeeding behaviour in Zambia in the general population, as the available literature was limited to studies conducted among HIV-positive mothers. The determinants of handwashing in other settings has been widely studied, however, we did not know whether these determinants were also important drivers of behaviour in our study context. Furthermore, we had little information on the home management of childhood diarrhoea and the factors influencing caregivers' choices. Other programmes targeting one or more of the target behaviours were known to be in operation, but their level of activity was unknown.

3.3 Overview of methods

3.3.1 Study setting and population

The Programme for the Awareness and Elimination of Diarrhoea (PAED) was introduced in Chapter 1, but the research setting was not. This section provides contextual information on the characteristics of Lusaka Province and the peri-urban and rural study sites selected for the formative research.

PAED was implemented in Lusaka Province. Lusaka is the smallest of Zambia's nine provinces, but it is the most densely-populated and urbanised area of the country (Central Statistical Office [Zambia] et al., 2014); two million of the country's (then) 13 million inhabitants reside in Lusaka (Central Statistical Office [Zambia], 2012). At the time the study was conceived, the province comprised four districts: Lusaka, containing 80% of the population of the province and the nation's capital; Kafue and Chongwe, two predominantly rural districts, each inhabited by approximately 10% of the population; and Luangwa, a rural, remote district populated by fewer than 20,000 people (Central Statistical Office [Zambia], 2012).

Lusaka district has the largest urban population in the country. Approximately two-thirds of Lusaka's inhabitants live in high-density, peri-urban settlements known as compounds (World Bank 2002). These slum areas grew as a result of rural-urban migration in the mid- to late-nineteenth century following rapid expansion of the mining industry. Whilst not all slums are unauthorised, they are

all characterised by poor access to amenities such as water supply, sewerage, electricity, roads, and waste management. People living in these underserved areas are largely unemployed or intermittently employed (Mulenga, 2003). Health facilities are relatively accessible except in a few areas, although the clinic catchment areas can be large (Ministry of Health [Zambia], 2013). In contrast, the other districts are predominantly rural and have a low population density. The main types of income generating activities in these rural areas are farming, fishing, charcoal burning and animal rearing. Most households do not have access to electricity, road networks, infrastructure or proper sanitation. Access to health centres is also a serious problem for many residents (Central Statistical Office [Zambia] et al., 2014).

As the majority of Zambia's citizens live in rural areas (Central Statistical Office [Zambia] et al., 2014) and PAED had ambitious plans for scale up following the end of the programme, it was important that the behaviour change intervention would be suitable for delivery in both peri-urban and rural settings. Formative research was thus conducted in both settings. Figure 3-1 shows some images that capture the main characteristics of the housing and environment in each study site.

Figure 3-1. Characteristics of the peri-urban and rural formative research study sites

The research took place in two purposively selected sites: George compound, a peri-urban, densely-populated 'slum' setting in Lusaka District; and Ngwerere Main, a rural site in Chongwe District which was easily accessible from Lusaka city. Additional research was planned in a middle-class urban area as a comparison site. However, it proved difficult to find participants willing or available to be interviewed or observed in this more affluent area. As this group was not the primary target of the behaviour change campaign, efforts were focussed in peri-urban and rural areas. We envisaged that primary caregivers of children under-five would be the main target of the intervention. We focussed on understanding practices within two sub-sets of this population: caregivers of children under-five with current diarrhoea recruited at health clinics; and caregivers of infants under-one recruited through random walk in the community.

3.3.2 Overview of formative research methods

This section serves to provide a brief overview of the methods used in the formative research study. The methods relevant to the investigation of ORS and zinc use behaviours are reported in more detail in Research Paper 1. Methods specific to the study of exclusive breastfeeding and handwashing with soap are reported in the following chapter.

Data were collected over three weeks in February and March 2013 following a week of intensive piloting of tools and training of research assistants. Data collection involved clinic observation at the government clinic in each study site, 14 behaviour trials involving use of ORS and zinc to manage under-five diarrhoea in the home, 15 direct observations of caregivers' behaviour over a four-hour period, 15 semi-structured interviews with these caregivers, 8 trials of handwashing behaviour, 7 focus group discussions and 11 key informant interviews. The methods used to collect data in the formative research are summarised in Table 3-2.

Table 3-2. Overview of data collection methods

Method	Behaviours	Description	Purpose	Sample
Clinic observations	General diarrhoea management	Unstructured observation of the activities taking place in and around the clinic, including use of ORT corners	To understand the role of the clinic in diarrhoea management and the lives of the target population	Government health clinics in peri-urban George and rural Ngwerere N=2 clinics
Behaviour trials (ORS & Zinc)	ORS & zinc use	A series of visits over 10 days to encourage correct preparation and use of ORS and zinc to manage a current diarrhoeal episode. Day 1: Interview, video observation of ORS preparation Day 3-6: Follow-up Day: 9-10: Follow-up	To provide participants with a chance to engage with the target behaviours and determine through experience any difficulties of performance and treatment preferences	Caregivers of children under-five with current diarrhoea on Plan A (home treatment of diarrhoea using ORS & zinc) N=8 peri-urban N=6 rural
Household observation	Handwashing with soap and infant feeding (exclusive breastfeeding)	Videoed, direct observation of household activities involving childcare over a four-hour period beginning at dawn	To document actual handwashing and infant feeding practices, the context in which they occur and any barriers	Caregivers of infants under-one N=8 peri-urban N=7 rural
Semi-structured interviews	Handwashing with soap and infant feeding (exclusive breastfeeding)	Follow-up interviews conducted after household observation involving a number of activities, including mapping of daily routines and social networks	To deepen understanding of current practices and the drivers of these behaviours, and to better understand life in the community	Same as household observation
Behaviour trials (Handwashing)	Handwashing with soap	A series of visits over 7 days to encourage handwashing with soap after defecation and before eating through co-location of soap and water at a handwashing location. Peri-urban: soap provided Rural: soap and a handwashing stand provided	To provide participants with a chance to engage with the target behaviour and determine through experience any difficulties associated with co-location of soap and water at a handwashing location	N=4 peri-urban N=4 rural
Focus group discussions	All behaviours	Group discussion with up to 10 individuals involving a number of activities and visual prompts to encourage the flow of conversation	To understand dominant cultural perceptions of the behaviours and key potential drivers of behaviour in more depth, namely: i) diarrhoea treatment solutions; ii) communication networks and motives; iii) infant feeding practices; iv) manners	Caregivers of children under-five N=7 focus groups
Key informant interviews	All behaviours	Unstructured interviews with different individuals covering various contextual aspects of current behaviours and the factors determining their practice.	To understand the behaviour change challenge from different perspectives, in light of data already collected	11 individuals: teacher, NHC, EHT, nurse, water tap reader, church leader, grandmother, pharmacy workers (x2), private doctor

Note: NHC = Neighbourhood Health Committee volunteer; EHT = Environmental Health Technician

3.4 Formative research: ORS and zinc

3.4.1 Preamble for Research Paper 1

In Research Paper 1, I present the formative research pertaining to the preparation and use of ORS and zinc. Trial papers sometimes state that formative research informed intervention development, but detailed accounts of formative research studies are rarely available. Not only does this mean that there are few examples to guide investigators, it also limits the ability to demonstrate the value of the rich data derived from such studies. I present the results according to categories of the Evo-Eco model of behaviour (Aunger and Curtis, 2014) to show how the findings related to the underlying theory of behaviour that informed the study methods. Further detail on this model can be found in Research Paper 1 and in Chapter 2, Section 2.5.

3.4.2 Research Paper 1

Theory-based formative research on oral rehydration salts and zinc use in Lusaka, Zambia

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Student	Catherine Elizabeth Greenland
Principal Supervisor	Dr. Val Curtis
Thesis Title	Unpacking the Black Box: Theory-Based Design & Evaluation of a Multiple Behaviour Change Intervention to Control Diarrhoeal Disease

If the Research Paper has previously been published please complete Section B, if not please move to Section C

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Where was the work published?	BMC Public Health		
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RESEARCH ARTICLE Open Access

Theory-based formative research on oral rehydration salts and zinc use in Lusaka, Zambia

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Abstract

Background: A theoretically grounded formative research study was carried out to investigate behaviour related to the use of Oral Rehydration Salts (ORS) and zinc tablets. The purpose was to inform the design of the behaviour change component of the Programme for Awareness and Elimination of Diarrhoea in Lusaka Province, Zambia, which aims to reduce childhood morbidity and mortality from diarrhoeal disease.

Methods: Fourteen behaviour trials were conducted among caregivers of children under-five with diarrhoea. Caregivers were recruited from two clinics situated in rural and peri-urban Lusaka. Trials took ten days and data were captured using video, observation and repeated interviews. Additional data were collected through focus group discussions with mothers, observations in clinics and pharmacies and interviews with clinic and pharmacy staff. Findings were organised according to categories of behavioural determinants from Evo-Eco theory.

Results: Participants were all familiar with ORS and most knew its purpose. ORS use was motivated by symptoms of dehydration, rather than the start of a diarrhoea episode, and was stopped when the child had visibly recovered energy. Only four of 14 behaviour trial participants were observed to correctly prepare ORS. Errors were mainly associated with measurement, resulting in a solution that was too concentrated. ORS was not observed to be given to children at clinics. Although zinc was unknown in this population, it was positively received by mothers keen to learn whether zinc would work better than alternative treatments to stop diarrhoea.

Conclusions: ORS was sub-optimally prepared and used at home. It was not used while waiting to be seen at a clinic. In homes, the behaviour change intervention should promote early and continued use of correctly prepared ORS. In the longer-term, these behaviours may best be encouraged by changing the product design or sachet size. Despite its unfamiliarity, this population was well disposed to the use of zinc as a treatment for diarrhoea; when zinc is new to a population, promoting zinc as a solution to stopping diarrhoea, which mothers seek, may drive initial trial. Ensuring the availability of zinc in public clinics and private pharmacies prior to commencement of any promotion activities is crucial.

Keywords: Formative research, Oral rehydration, Zinc, Diarrhoea prevention, Intervention design, Behaviour centred design

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Background

Despite declines in overall child mortality, as well as in diarrhoeal deaths over the last 10 years [1, 2], diarrhoea remains the second leading cause of child deaths globally [2]. It was estimated to cause over half a million (0·448–0·750 million) deaths among children under-five in 2013 [2]. Though oral rehydration salts (ORS) are known to prevent and treat dehydration, the major cause of death from diarrhoea, their use is far from ubiquitous [3]. ORS has been available since the 1970s, when its initial introduction was accompanied by intense promotion efforts [4, 5], but funding and interest in diarrhoea control subsequently waned. Despite renewed attention and the development of more effective, low-osmolarity ORS in the early 2000s [6], ORS use remains low, and has even declined in many countries [7], with only a third of childhood diarrhoeal episodes estimated to receive ORS in sub-Saharan Africa [6].

More recently, zinc supplementation has been shown to be an important complement to ORS, reducing the duration and severity of diarrhoeal episodes [8]. A complete 10–14 day course of zinc supplement can also reduce subsequent incidence of diarrhoea [8]. WHO and UNICEF have recommended zinc supplementation and ORS for the routine management of acute childhood diarrhoea since 2004 [9]. Zinc has been introduced via the private sector and included on the 'essential drugs' list in the Integrated Management of Childhood Illnesses (IMCI) package in many countries. However, it is still not procured in sufficient quantities to meet needs, and is not widely purchased and sold in the private sector [6, 10]. Whilst it has been estimated that universal coverage and use of ORS and zinc to treat diarrhoea could prevent three-quarters of diarrhoea-associated mortality [11] and promotion of zinc may help to drive ORS uptake [9], there is limited information about how best to promote ORS and zinc.

In Zambia, the risk of a child dying before their fifth birthday is high (75 deaths per 1000 live births), with diarrhoea the cause of 1 in 5 of these deaths [12]. Sixty-four percent of diarrhoeal episodes among children under five are reported to receive ORS [12], but Zinc use is negligible. Despite higher reported use than elsewhere in the region, a 'LisT' analysis placed the promotion of ORS third on the list of interventions that could save the most child lives in Zambia [13].

The Programme for Awareness and Elimination of Diarrhoea (PAED) aims to reduce childhood morbidity and mortality from diarrhoeal disease through strategies including the use of ORS and zinc for the home management of child diarrhoea in Lusaka Province. A formative research study was carried out to inform the design of the ORS and zinc promotion component of the programme.

This work was guided by the 'Behaviour Centred Design' (BCD) approach [14], a process for designing behaviour change interventions. Central to this is the Evo-Eco model of behavioural determinants (Fig. 1) [15]. The model proposes that the brain controls behaviour in three major ways: some actions are automatic responses to cues; others are driven by a motive such as fear or affiliation to reach particular evolved goal states such as safety or social acceptance; and others originate from conscious, cognitive decisions that result from internal evaluation of the – often longer-term - consequences of different courses of action [16]. A person's actions are also influenced by aspects of their physical, social and biological environment which determine most routine and recurring behaviours – the 'setting', in which the behaviour takes place [17].

The BCD approach also outlines five essential steps for the design and testing of behaviour change interventions: ***A**ssess* what is known and what is not known about the behavioural problem; ***B**uild* on this understanding by carrying out formative research; ***C**reate* a theory-based intervention; ***D**eliver* it; and ***E**valuate* it [14, 18]. This paper concerns the *Assess* and *Build* steps for ORS and zinc promotion for home management of childhood diarrhoea in Lusaka, Zambia. Other aspects of the formative research are described by Chipungu et al., (In prep). Findings from the evaluation of the intervention developed as a result of this research will appear elsewhere.

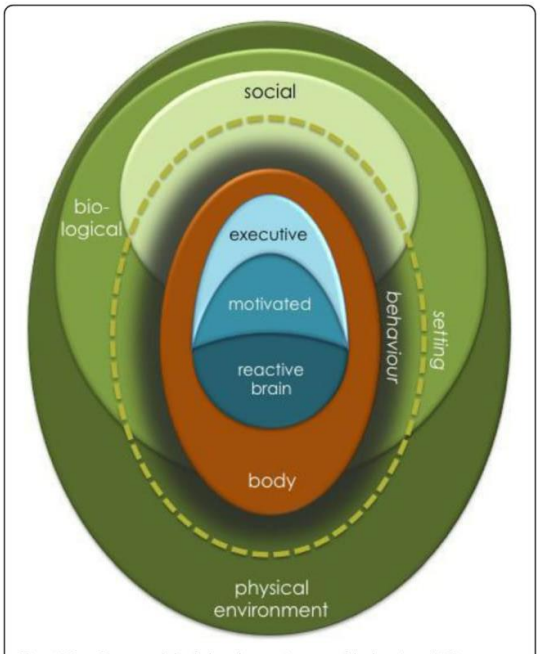

Fig. 1 Evo-Eco model of the determinants of behaviour [15]

Methods

Study setting and population

The study was conducted in Lusaka Province, Zambia, which is comprised of four districts and is home to just over 2 million of Zambia's 13 million inhabitants [19]. Eighty percent of the province's population reside in Lusaka District, the majority in peri-urban slums known as 'compounds'. These areas are characterised by high population density and poor access to water supply, electricity, roads, waste management and sanitation. The remaining three districts in Lusaka Province are rural and sparsely populated, with houses more geographically distant from health centres and other facilities.

The main target of the behaviour change campaign was envisaged to be primary caregivers of children under-five in peri-urban and rural settings. Accordingly, two research sites were selected in a peri-urban compound in Lusaka District and in a rural area in Chongwe District.

Assess: Framing the research questions

Following the BCD process, the first step was to assess what was known and not known about use of ORS and zinc in home management of diarrhoea to determine the parameters of the formative research. A framing workshop was convened to review evidence from published journal articles, grey literature and expert knowledge on the practice of the target behaviours and their determinants in Zambia and elsewhere. Though some reports on clinic prescribing practices and reported use of ORS from household surveys were located, little was known about how caregivers prepared and used ORS to manage diarrhoea at home. The Assess stage also established that the supply of zinc via government health centres and private pharmacies (drug stores) was unreliable. Three objectives for the formative research were set:

1. Define current behaviour and what precisely needs to be changed (target behaviour) and by whom (target audiences).
2. Investigate the determinants of current practices and the context in which they occur, in order to identify how change may be brought about.
3. Explore how people communicate currently to identify channels that could be used to reach the target audience (*not described in this paper*).

Build: Formative research methods

In keeping with our theoretical focus on behaviour, the research concentrated on documenting behaviour and its unconscious drivers rather than on what people said that they thought, did or believed. Consequently, data were primarily collected through observation of behaviour in context and behaviour trials [20]. Data were collected iteratively until researchers were satisfied that all topics had been adequately covered.

Behaviour trials

The clinical management of diarrhoea in Zambia has a standard protocol: children with no dehydration are put on 'Plan A' and sent home with ORS, zinc, and any other necessary medications; moderately-dehydrated children are put on 'Plan B' and are observed receiving ORS at an oral rehydration therapy (ORT) corner before they are reassessed; and children that are more severely dehydrated are admitted and receive intravenous fluid, known as 'Plan C' [21]. A convenience sample of caregivers with a child under five with diarrhoea on 'Plan A' treatment were recruited after they had collected their medications at the pharmacy in the government clinics in the two study sites. Zinc was provided to the pharmacies to ensure that recruited mothers would receive a full and correct course.

The behaviour trial involved three separate home visits during a 10 day period. The first visit was on the day of recruitment. The purpose of the study was explained to the participant, written informed consent was obtained and they were accompanied home from the clinic. They were then interviewed about the child's diarrhoea and were observed and videoed as they prepared ORS solution using the sachet they had been given by the clinic. Corrections were made as necessary at the end of the visit. Participants were provided with three additional sachets of ORS and were encouraged to buy more (to be reimbursed) if needed. The ill child was observed taking the first zinc tablet during this visit. Information on the purpose of zinc and how it should be administered (once daily) was provided and the participant was left with a calendar as a daily reminder to give zinc. Two further visits were made, once between the 3^{rd} and 6^{th} day after recruitment and again on the 9^{th} or 10^{th} day. Participants were interviewed on each visit using a topic guide and the presence of ORS and number of remaining zinc tablets were documented. All interviews were voice-recorded.

Focus group discussions and key informant interviews

Four focus group discussions were conducted in both study sites with female primary caregivers of children under-five not participating in the behaviour trial. Up to 10 caregivers were identified by a Neighbourhood Health Committee volunteer; group size was restricted to encourage participation. Projective techniques [22] were used to explore motives behind decisions to give ORS and zinc by inviting the participants to select cards depicting different human motives to explain how a comic strip story of a child with diarrhoea could best be concluded. Picture-sorting exercises were also used to explore how ORS and zinc were classified and understood in the context of other treatments. A probing

topic guide was used to direct discussion to cover common practices and perceptions about diarrhoea, its causes and impact on the mother, and knowledge and opinions of available traditional and biomedical treatment of diarrhoea.

Clinic and pharmacy visits

Unstructured observations were carried out over 2–3 h in clinic waiting rooms and ORT corners in both clinics during recruitment for behaviour trials. Private pharmacies (drug stores) in the vicinity of the clinics were visited. Short, semi-structured interviews were conducted with three health workers at public and private health clinics and two pharmacy shop workers to understand caregiver treatment-seeking practices and provide insight into provider behaviour.

Piloting and training

Data collection tools were field tested and revised prior to and during a week of intensive classroom and practical training. By the end of training all team members were knowledgeable about ORS and zinc and understood how to observe behaviour and probe appropriately during interviews and discussions.

Data handling and analysis

The videos of ORS preparation were reviewed and a summary narrative was produced. ORS preparation was divided into four stages according to guidelines for preparation [23] and instructions for use on ORS sachets in Zambia: 1) use of safe water, i.e. chlorinated water or water that has been boiled; 2) measurement of 1 l of water, measured after boiling, if applicable; 3) use of the whole sachet of ORS, put into 1 l of cooled water (if applicable); and 4) the prepared ORS covered appropriately to prevent contamination. The summary narratives were then used to ascertain which stages of preparation were associated with error. All audio recordings of interviews and focus group discussions were transcribed. QSR International's *Nvivo* 10 qualitative data analysis software was used to organise transcripts and to code segments of interviews into nodes related to use of ORS or zinc based *a priori* on the 'Evo-Eco' determinants of behaviour. This coding was used to identify emergent determinants related to the use and preparation of ORS and the use of zinc.

Results

Characteristics of study participants

Fourteen caregivers in the peri-urban ($n = 8$) and rural ($n = 6$) study areas participated in behaviour trials between February and March 2013. All were the mothers of the ill child with the exception of one grandmother. Two of the individuals approached declined to participate, stating that they were not returning home after the clinic. Socio-demographic characteristics of participants are presented in Table 1. Four focus groups were also held with groups of 7–10 mothers of children under-five in the peri-urban ($n = 2$) and rural ($n = 2$) communities.

Table 1 Socio-demographic profile of behaviour trial participants ($N = 14$)

ID	Age of mother (years)	Age of ill child (months)	Marital status	Occupation	Occupation of main breadwinner	Household monthly income (ZMK)	Mother's education level	HH size
GEORGE ($n = 8$)								
1	46–50*	54–59	Married	Self-employed	General worker	500-100	Primary	8
2	21–25	12–17	Single	Unemployed	Unemployed	Unknown	Primary	11
3	21–25	18–23	Divorced	Unemployed		<500	Primary	14
4	26–30	18–23	Married	Self-employed	Manual labourer	<500	None	6
5	21–25	24–29	Married	Self-employed	Businessman	500-1000	Primary	4
6	26–30	6–11	Divorced	Self-employed		500-1000	None	8
7	16–20	0–5	Married	Student	Businessman	>1000	Some secondary	3
8	21–25	18–23	Married	Unemployed	Salaried job	500-1000	Some secondary	3
NGWERERE ($N = 6$)								
1	21–25	12–17	Married	Self-employed	Businessman	<500	Secondary	5
2	21–25	60	Divorced	Unemployed	Businessman	<500	Some secondary	3
3	21–25	12–17	Single	Unemployed	Agriculture	<500	None	5
4	26–30	12–17	Married	Unemployed	Manual labourer	500-1000	Primary	4
5	21–25	30–35	Married	Unemployed	Businessman	500-1000	Some secondary	4
6	26–30	18–23	Divorced	Self-employed		<500	Primary	3

*Caregiver is the child's grandmother

Clinic characteristics

Clinics in both study sites were clean at the time of our unscheduled visits, and had functioning toilets and space to wait within the clinic and its surroundings. Many patients had gathered before the clinics opened and the peri-urban clinic was especially crowded. Waiting times were several hours in both clinics. Queues were shorter in rural clinics, but there were fewer attending staff.

Despite dozens of cases of diarrhoea passing through the clinics during the period of observation, the ORT corners at both clinics remained unsupervised and unused. The clinic pharmacies had ORS but only one or two sachets were given per queueing patient. Courses of 10 zinc tablets were cut in half in the rural clinic; reportedly because of limited supplies. Staff admitted failing to write a prescription for zinc as it is not always available for purchase elsewhere. Two private pharmacies in the vicinity of the peri-urban clinic had small quantities of ORS and zinc, but sales staff (who were not qualified pharmacists) could neither correctly describe how to prepare ORS, nor knew the dosage and function of zinc. No pharmacies were found near the rural clinic.

Caregiver behaviour

Findings concerning the three behaviours of interest are presented below: 1) ORS use; 2) ORS preparation; and 3) zinc use by caregivers. The behaviours are first described, followed by the possible determinants of current practices. The latter are organised according to the categories in the Evo-Eco model of behaviour and are summarised in Table 2.

Behaviour 1: Insufficient early initiation and continued use of ORS

ORS was often given at home soon after a child had fallen ill with diarrhoea, but use of ORS was not always initiated at the onset of diarrhoea and did not continue until the end of the episode as recommended.

During the time between onset of diarrhoea and presentation at the clinic up to five days later, 10 of the 14 behaviour trial participants claimed to have given their child homemade sugar-salt solution ($n = 4$) or manufactured ORS ($n = 6$) that they had at home or had borrowed from a neighbour. Other medicines, including paracetamol ($n = 6$), metronidazole antibiotic and antiprotazoal medication (Flagyl™) ($n = 3$) and anti-malaria medications ($n = 1$) were also given at home before treatment was sought from a clinic. Use of traditional remedies was only reported by one trial participant, although further discussion in focus groups indicated that their use is quite common in these communities:

> *'We cause a lot of deaths because we like to start with this same Bemba style [traditional medicine]. It is rare for us to rush first to the clinic' (Focus group participant, Peri-urban).*

ORS solution or half-empty sachets were found in three homes during the first visit conducted immediately after recruitment. Six children were still ill with diarrhoea at the time of the first follow up visit; ORS solution was found in just one of these households.

Factors influencing Behaviour 1: Insufficient early initiation and continued use of ORS

Factors in the Brain

At the executive level of behavioural determinants, *knowledge* of ORS use was high. In particular, all caregivers had heard of ORS and almost all understood that it does not stop diarrhoea.

> *'When the child has diarrhoea, the child loses water, so when you prepare this [ORS], you can then give the child as many times as possible.... So that the water in the body can be replenished' (Mother, Peri-urban).*

Most *knew* that it should be given before going to the clinic and *believed* that ORS restored energy in a [dehydrated] child, from the experience of seeing the effects on their own or other children (all caregivers had used ORS previously). Few *knew* that ORS solution should be given throughout the course of the episode. Few mothers *planned* for possible diarrhoea by keeping a stock of ORS ready in the home, or *intended* to give the child ORS regularly until the diarrhoea stopped.

At the level of motivation, the '*nurture*' motive emerged as an important driver of action; caregivers worried about their ill children and acted accordingly:

> *'When I was taking him to the clinic, he scared me. Every time I looked at him, he was quiet. When I would carry him, he could not even cry.' (Mother, Rural).*

Their primary reason for seeking treatment at the clinic was to stop the diarrhoea, and mothers reported feeling frustrated when they were given only ORS. Nevertheless, ORS, which is known locally as *'manzi yamoyo'* (water of life), was valued for use when a child was ill and lacked energy to eat or play. Mothers' motivation to continue ORS once a child had visibly recovered energy, however, was low:

> *'Even just after the child has finished this amount, the child will have enough water in the body.... Well, because of the way the child appears, if the child looks*

Table 2 Factors influencing use of ORS and zinc in the management of childhood diarrhoea by theoretical construct

	Insufficient early and continuous usage of ORS	Incorrect preparation of ORS	Trial of zinc
FACTORS IN THE BRAIN			
Executive *Deliberate planning, knowledge*	Awareness of ORS and its purpose to replace fluids is well-*understood* - caregivers know that it does not stop diarrhoea	Limited *knowledge* of the importance of preparing correctly-concentrated solution as ORS is considered to work like rice water or an energy drink	Zinc is *unknown* and thus not part of current suite of medicines considered to treat diarrhoea.
	Some *knowledge* that ORS should be given from onset of diarrhoea but lack of knowledge that it should be given throughout the episode	High level of *knowledge* regarding the use of clean water for ORS preparation but limited knowledge that 1 packet of ORS needs to be prepared with 1 l of water	*Belief* that injections/antibiotics are the best way of stopping diarrhoea
	Planning: ORS may not be stocked at home ready to use		*Planning*: Zinc is not kept at home so is unavailable as a choice of treatment at start of diarrhoea episode
Motivated *Emotional drivers, interests, reward*	It is *rewarding* when children respond to ORS (energy, play, eat). When a child is visibly sick (listless, dehydrated) mothers respond with ORS	*Hoard:* small volumes of ORS deliberately prepared using part sachets to avoid wasting limited supplies or preparing ORS that is not consumed by the child	*Nurture:* eager to stop diarrhoea in their child (and other family members with diarrhoea)
	Nurture: Mothers primarily seek treatment to stop diarrhoea so ORS is not highly valued	*Affiliation:* eager to learn how to prepare ORS correctly for social approval	*Curiosity:* keen to see whether zinc is as 'strong' as other diarrhoea medicines
	ORS is given away or is sold cheaply so is not highly *valued*	*Hunger/Thirst,* ORS given more easily when child complains of thirst	*Hunger:* Zinc tastes unpleasant but children could be persuaded to take it.
Reactive *Cues, habits & skills*	ORS initiation is *cued* in response to dehydration rather than at onset of each diarrhoeal episode and discontinued when child visibly recovers	*Cue* to stop adding ORS sachet contents to water is when it 'tastes right'	Reminders were often needed to *cue* daily zinc administration and to give zinc for 10 days
FACTORS IN THE ENVIRONMENT			
Physical *Objects/tools, infrastructure*	Few ORS *sachets* are given at clinic, limiting ability to give ORS throughout diarrhoeal episode without purchasing more or returning to the clinic	Many households lack a *container* to measure 1 l of water. 'Banana cups' no longer found frequently	Zinc in *blister packs* or unmarked plastic bags look like common painkillers
	It takes appreciable time and charcoal to boil water on a *brazier* that is needed for multiple purposes	*Sachets* to make up smaller quantities of ORS are not available	
	Caregivers move around during the day and carrying ORS *solution* can be awkward	Water is hauled from *standpipes* and stored in *containers* in the house	
Social *Role models, relationships, networks, norms, institutions*	Waiting time to get prescription and then get ORS dispensed at *clinic* is high	*Neighbours* may lend ORS and give previously used or left over medications	Lack of accountability for giving zinc when shared with multiple *family members*
	Lack of private *pharmacies* in rural areas	*Clinics* give only one or two sachets of ORS, often after queuing for a long period	People talk. They share experiences of remedies that work and trial them.
	Older (female) *relatives and neighbours* advise on appropriate treatment		Clinic *pharmacies* are the main source of medicine, but zinc is often unavailable and may not be given/prescribed. Lack of availability in private sector in rural areas even if affordable.
	Illness may be concealed because people can *gossip* about why a child is ill		Clinic staff are trusted to determine the correct treatment
Biological *Parasites/foods/animals*	*Diarrhoea* is a common phenomenon	Home environment is hard to keep free of *contamination* (lack of running water/hard surfaces, cleaning equipment, toilets, etc.)	

energetic and the body seems to have regained its form, you can then stop' (Mother, Rural).

Hence, though mothers *knew* that ORS should be given from the onset of diarrhoea, in practice they responded with ORS only when a child was thirsty, crying and visibly suffering, signs of which *cued* a nurturing response. Once these signs stopped, ORS use stopped also.

Factors in the Environment

Physical factors in the environment that constrained the early initiation of ORS use were its lack of immediate availability and the physical difficulties of preparing it. ORS was not usually present at home and a visit to a clinic often required an early start and change of plans for the day. Once ORS had been acquired, often after a long wait, preparation was also time-consuming as water was generally boiled and cooled. This further delayed receipt of ORS by the ill child.

This conversation with one peri-urban mother illustrates the issues:

Researcher: *'Have you made fresh ORS?'* Participant: *'No not yet. I have just finished cooking rice so the brazier is now free and I can boil the water. Now, he kept saying amu amu, so I figured he was hungry and opted to cook the rice first.'* Researcher (later in the conversation): *'Why have you not made any ORS up to this time?'* Participant: *'I don't have boiled water'.* Researcher: *'Are you boiling some now?'* Participant: *'No, I am boiling some for tea first.'* Researcher: *'How do you usually make it? Do you get water from the water that you are boiling for tea or do you boil the water for ORS separately?'* Participant: *I wait for the school-going children to finish cooking their food first then I boil the water for ORS.'*

Once initiated, running out of ORS sachets constrained the continued use of ORS, even in this study where three sachets were provided:

'I saw that she had some energy so I thought if I make any more it will get spoilt… The clinic doesn't give any [ORS], so this one will help later on.' (Mother, Peri-urban).

Early initiation and continued use was also influenced by *social* factors. Mothers disliked having to reveal that their child was ill, fearing gossip and stigma, hence hoped that an episode would self-limit and not have to be acknowledged publically in a clinic visit.

'People like to gossip… Some would say I neglect the child and that is what is causing the child to get diarrhoea' (Mother, Peri-urban).

Eight of the 14 participants lived with a mother or mother-in-law. These older women recommended use of ORS when a child shows symptoms of dehydration:

'My mother is the one that used to tell [when the child needed ORS], she would just say I am an elderly woman, I know… [Researcher: What did she do?] She was checking the child's eyes and hands.' (Mother, Rural).

Diarrhoea was seen as an inevitable fact of life that occurs often, for example in association with teething, and which resolves spontaneously. Together these factors conspired to desensitise mothers to the potential severity of diarrhoea, a common *biological* factor in the environment.

Behaviour 2: Incorrect preparation of ORS

Video data showed that ORS was prepared sub-optimally (Table 3) with errors at all stages.

Only four of 14 participants prepared ORS correctly, i.e. measured a litre of cool clean water and mixed in a whole sachet of ORS. All caregivers used or attempted to use water that was either boiled or chlorinated or both. Boiling water for drinking was not normal practice, and it took substantial time and effort, sometimes more than an hour, to accomplish this. In two cases someone had to first fetch charcoal from the local market. The quantity of water was measured correctly by six caregivers, although three of them measured before boiling the water which is not recommended. The remainder either did not measure the water at all ($n = 5$) or measured an incorrect amount ($n = 3$), so that the resulting solution was typically too concentrated. In four instances the caregiver used only part of a sachet, mixing it in until satisfied with the taste.

Factors influencing Behaviour 2: Incorrect preparation of ORS

Factors in the Brain

As far as the executive control of behaviour is concerned, mothers had mixed *knowledge* of ORS. It was described as *'glucose'* and *'just* water' and was classed with 'rice water' by focus group participants who saw the two liquids as fulfilling a similar function in rehydrating a child. ORS was not viewed as a medicine and there was no *knowledge* that the wrong concentration of the prepared solution could adversely affect the child. Women who were more familiar with preparing homemade sugar-salt solution added and mixed ORS sachet contents using taste as a *cue* that they had prepared the correct concentration.

Table 3 ORS preparation by behaviour trial participants ($N = 14$)

ID	Summary of observed ORS preparation	Prepared using clean water?	1 l of water measured?	Whole sachet added, into cool water?	Solution covered?	ORS prepared correctly according to all criteria?
GEORGE						
1	Took a bowl, washed jug in the bowl, took water from stored (chlorinated) water using a banana cup (500 ml) and measured two cupfuls into the jug. Mixed in whole sachet of ORS with spoon. Poured ORS into a kettle and covered with bowl.	Yes	Yes	Yes	Yes	Yes
2	Took water from bucket (said to be chlorinated). Boiled some water, didn't wait enough for it to cool *"The water is meant to be cooled after boiling but I did it this way because you said you wanted to see me making it"*. Shook some of the ORS sachet into large plastic cup, tasting and adding more several times. Then washed container (large plastic bottle with lid) she will store ORS in & will cover it. Jar leaks so put on dish.	Yes	No	No	Yes	No
3	Used boiling water and added sachet directly, didn't add everything but folded over sachet and kept remaining, didn't measure water at all, put it in a plastic jug (not 1 L).	Yes	No	No	No	No
4	Started to make by boiling water on stove (was taught by clinic a long time ago – 1 year), then power went off and she just made in a jug with normal water they have (not treated). Used 3 large plastic cups to measure 1 L (we checked, was correct) into large saucepan. Used whole sachet. Said will clean milk container very well with soap and will store it there. Said they usually boil water on a charcoal fire but hadn't started fire yet as she was at the clinic which is why used stove. Will keep ORS until the next day. Will cover ORS.	No	Yes	Yes	Yes? (Not observed)	No
5	First mentioned need to start brazier to boil water, then mentioned that stored water was chlorinated so agreed to make the ORS using this water. Washed a spoon, poured some of sachet contents into a large plastic cup of the chlorinated water.	Yes	No	No	Not while researcher was present	No
6	Boiled water on a brazier inside house. Waited for water in saucepan to cool. Put entire contents of sachet into one banana cup (500 ml) of the boiled water.	Yes	No	Yes	Not while researcher was present	No
7	Says uses "own initiative to boil water first". Boiled *some* water in a saucepan. Said she would wait for water to cool. As volume was already incorrect (and ORS would need remaking), researcher asked her to go ahead and prepare the ORS. She added the whole sachet of ORS to the water in the saucepan and stirred with spoon.	Yes	No	Yes	Not while researcher was present	No
8	Uses water purifier sachets to clean water. Four sachets seen in baby bag. Water taken from bucket in kitchen using metal tea pot. Mother has 2 L and 2.5 L containers only. After making ORS mother observes volume is too much. Mixes whole sachet. Keeps ORS in covered metal pot.	Yes	No	Yes	Yes	No
NGWERERE						
1	Makes fire on brazier with charcoal (takes about 5 mins to light, then a long time to heat before can add saucepan of water). Did not observe measurement so must have been before boiling - Mother reported using 1 L sour milk container to measure when questioned. Puts whole sachet of ORS into saucepan but doesn't stir. Covers with lid.	Yes	Yes (measured after boiling)	Yes	Yes	Yes
2	Sent someone to go and buy charcoal and then lit fire, took a long time for water to boil. Poured from saucepan into a jug with a lid. Didn't measure water at any point. Was about to pour in sachet to complete when we stopped her [so as not to waste the sachet]. Knows how to measure one litre: 3 ½ cups (we checked)	Yes	No	Yes	Not while researcher was present	No

Table 3 ORS preparation by behaviour trial participants ($N = 14$) *(Continued)*

3	15 years old brother-in-law made fire with charcoal which used to boil water. Father went to buy charcoal from nearby market. Mother measures 5 glasses of water (about 1 l) into saucepan and then boils water in large pot. Pours water into plastic jug and covers with lid. Leaves to cool. Adds sachet (not observed)	Yes	Yes (measured after boiling)	Yes	Yes	Yes
4	Boiled water. Cooled in saucepan placed in bucket of cold water. Poured water from saucepan into plastic kettle (2 L capacity). Believes measurement is 2 L. Adds whole sachet and stirs. Puts lid on kettle.	Yes	No	Yes	Yes	No
5	Took a while to light brazier and heat coals. Measured 3 large plastic cups of water into a kettle and boiled water. Rinsed a bowl and poured boiling water into it. Left to cool. Added part of sachet only.	Yes	Yes(measured after boiling)	No	Not while researcher was present	No
6	Is very quick. Mother has firewood already burning, water boils v quickly. Pours from saucepan into 1 l large cup and transferred to larger jug and left to cool (covered). Mixed in whole sachet and mixed by pouring between two containers. Will keep in jug with a lid.	Yes	Yes	Yes	Yes	Yes

Knowledge about use of clean water was high, but knowledge on the need to measure 1 l of water was poorer.

Mothers preferred to make up smaller quantities than the recommended litre, so as not to waste any solution that the child would refuse to drink (the *hoard* motive).

> *'The child does not finish drinking 1 litre… It is very wasteful for me to make so much which I end up pouring away. This is why I have opted to make it in a cup so I can save the remainder to make later if needs be' (Mother, Peri-urban).*

At follow up visits caregivers were keen to demonstrate their ORS preparation skills and volunteered that they would be happy to teach others the same (*affiliation* motive).

Factors in the Environment

The physical environment challenged ORS preparation in several ways. Making ORS required a number of objects (brazier, charcoal, saucepans, a vessel to measure water, a container and lid to store the ORS to prevent contamination, etc.), many of which were borrowed from neighbours. Water for ORS was measured using different sized cups and containers, none of which were standard across households and most of which were of unknown capacity. Some caregivers were familiar with earlier teaching to use the 'banana cup' (500 ml) to measure out water, but these cups were no longer in common use.

Behaviour 3: Trial of zinc for diarrhoea treatment

Zinc was not used for diarrhoea treatment by this population prior to our study. No behaviour trial participants and only two focus group participants reported having used zinc on a previous occasion.

Zinc was administered daily throughout the 10-day trial by almost all participants, as requested. They invariably dissolved the tablet in water on a spoon or in a cup before giving it to the child and the tablet was halved to give the correct dosage for the child under six months. Zinc suspension was observed to be spat out by several young children, suggesting that they did not like the taste. One participant discontinued the zinc course at day three of the 10-day course. Nine participants gave the child the full course of tablets, although half of the participants had given the child an incorrect number of tablets by the time of the second ($n = 4$) or third ($n = 5$) visits; in general only one or two tablets were missed.

Factors influencing Behaviour 3: Trial of zinc for diarrhoea treatment

Factors in the Brain

Only one behaviour trial participant had prior *knowledge* of zinc. According to one pharmacy worker, if the medicine prescribed is expensive or unknown to the client (like zinc), they can be reluctant to spend money to try it. Caregivers indicated that they select a course of treatment based on remedies they know and consider effective:

> *'I like this medicine [zinc], it is effective. I have never used it before; this is my first time.... If I was given medicine at the clinic and thought it was not effective, I would resort to using traditional remedies like Mulberry trees and Musiniga trees then give the child to drink' (Mother, Rural).*

As zinc is not currently used it is not available at home, nor procured at the start of a diarrhoeal episode, nor considered as a treatment option.

The *curiosity* and *nurture* motives probably contributed to the good reception of zinc amongst mothers and their positive reactions to the behaviour trial. They reported being curious to see if zinc could really stop diarrhoea as well as their preferred treatments such as injections and antibiotics which they *believed* had superior effects. In three households zinc tablets were taken by other family members who had diarrhoea and wanted to see if the zinc would stop it. More than one child was reported to dislike the *taste* of zinc, but caregivers indicated that this was the case with other medicines too and did not affect ongoing use during the behaviour trial:

> *'You can't stop when the child refuses, you just have to continue persuading the child until he finally gives in and takes the medicine' (Mother, Rural).*

> *'I increase the water so that even when he has spat it out, there is still some left over in the stomach. So that's what I have been doing. I hold him down and give him the medicine. He spits out a little. I did the same today' (Mother, Rural).*

Two caregivers disguised the tablets by dissolving them in another drink, while several others reported that they had enlisted the help of another family member or the father who had more authority.

At recruitment many participants insisted they would not forget to give zinc daily as the presence of their ill child would act as a *cue* to remind them The trial calendars received a mixed reception: some used it, others had the calendar on the wall but did not own a pencil to check the days off, while others reported the calendar lost or damaged. Some mothers took the initiative to keep zinc in a place that was visited daily but out of the reach of children, such as a laundry basket. This proved

a successful reminder, as did setting alarms on mobile phones (when charged).

Factors in the Environment

The *physical* form of zinc in generic blister packs and its unfamiliar name caused two caregivers to confuse zinc with paracetamol. Clinic staff reported that they often remove tablets from their packaging and put them into clear, unmarked plastic bags, a further possible source of confusion.

Lack of choice of treatment options, particularly injections to stop diarrhoea in government clinics, was described by a doctor as a reason why those who could afford it used the private sector. This was explored and confirmed in discussion with caregivers:

> '*When I go to the clinic I go with the expectation that they will give the child an injection and sometimes the child is given only panadol [paracetamol]… What will the Panadol do?' (Focus group participant, Rural).*

Personal experiences and the opinions of others are important *social* factors influencing treatment choices: zinc is simply not known. The limited supply of drugs at clinics and lack of availability in the private sector in rural areas reduces the opportunity for caregivers to use zinc.

In some households zinc tablets were given by more than one adult. This caused confusion and resulted in children missing tablets on multiple days.

Discussion and conclusions

This formative research study explored behaviour concerning ORS and zinc and its determinants in the home management of childhood diarrhoea in a rural and urban setting in Lusaka Province, Zambia. The study was conducted to inform the design of a behaviour change campaign.

Behaviour regarding ORS use was suboptimal: no participants used it for the full duration of the diarrhoeal episode and only four prepared ORS solution correctly. Most concerning was the time taken to initiate oral rehydration therapy and the frequent preparation of overly-concentrated ORS solution, as both actions can affect the ability of ORS to replace fluids and correct electrolyte imbalances [5, 24].

Despite caregivers' reports to the contrary, ORS administration at the outset of a diarrhoeal episode is slow. Diarrhoea is common and a clinic visit takes time and is delayed. This pattern of behaviour in care-seeking is consistent with other studies [25–27]. However, as ORS sachets are typically obtained at the clinic, early initiation of ORS is also delayed. Avoiding a clinic visit may also avoid speculation in a close-knit community about the child's illness and possible HIV status; 'disease stigmatisation' [28] is documented in Zambia [29–31] and elsewhere [32]. Once at a clinic, waiting times and lack of staff available to supervise ORS use at the ORT corners further discourages early use. The final delay in initiation of ORS comes during its preparation: boiling water is cumbersome and may be delayed or avoided altogether. A study in rural China found that ORS use was positively correlated with habitually boiling drinking water [33]. Once a child looks better there is little incentive to continue to prepare new ORS solution. The low number of ORS sachets provided per person at the clinic does not help to reinforce the recommendation that ORS should be given daily while diarrhoea persists.

When caregivers prepare ORS solution that is too concentrated it is because they mix all or part of the sachet contents into an insufficient quantity of water, either to avoid wastage of solution or salts or while making ORS to taste. Manufactured ORS has been shown to be more effective and safer than homemade sugar-salt solutions [5]. It is also generally considered safer because of consistent errors in the measurement of sugar and salt for homemade ORS [21]. Change over time in the messages accompanying co-promotion of both forms of ORS has inadvertently caused confusion. Using only part of a sachet to conserve – or *hoard* - the rest is a natural human tendency. Evolutionary biology tells us that such a motive was adaptive for ancestors who lived in resource-scarce environments [34]. This practice is not unique to this study setting [35]. Hoarding ORS may also be connected with the number of sachets provided by a clinic; availability of ORS at clinics and use of ORS are closely related [33, 36].

There was almost universal lack of awareness of zinc as a diarrhoea treatment, which reflects the limited supply of zinc to government clinics and absence of published studies on zinc promotion in Zambia. Nevertheless, caregivers complied well with recommended behaviour concerning zinc use. Zinc was well-accepted because it was received at the clinic and couched as a medicine that stops diarrhoea, thus meeting the needs of caregivers who were actively seeking treatment. Our finding that caregivers strongly believe in the efficacy of injections and antibiotics is not new [37–39]; if caregivers find that zinc does indeed limit the length of episodes, the widespread introduction of zinc use may help to counter these expectations.

These formative research findings are important because of their implications for intervention design. Encouraging caregivers to give ORS solution early and to continue throughout a diarrhoeal episode to prevent dehydration, rather than just treat its symptoms is challenging: it is hard to motivate people to do something when the reward is not immediate, or obvious. We need to find ways to make such behaviour more rewarding. *Nurture* – caring for a growing child - is an important and essential motive

that affects child development [15, 40]. The nurture motive is likely to be a strong driver of good ORS practice for the duration of marked sickness, but not for prolonged correct use. As mothers wish to avoid social judgements about their child's health or their childcare abilities, an intervention could also explore use of *affiliation* or *status* motives [34, 41] as emotional drivers of behaviour change.

There are differences of opinion about the role of knowledge as a driver of behaviour; campaigns based on health education are often ineffective at instigating change in the target behaviour [42]. However, as skill levels affect a person's capacity to perform certain behaviours, improving caregivers' ability to prepare ORS through intervention could be important. 'Action knowledge' [43] such as this is a prerequisite for behaviour [44, 45]. In this case, lack of knowledge was not the only cause of incorrect ORS preparation, as mothers sought to economise by using only part of a sachet, leading to measurement error. Changing the design of the ORS sachets could improve correct preparation without an explicit intervention to change behaviour. Several investigators, including the Diarrhoea Working Group at the UN Commission (through CHAI and PATH) and ColaLife in Zambia have explored the potential market for smaller sachets. The latter organisation's *'Kit Yamoyo'* has demonstrated that use of the kit's packaging can improve correct preparation and directly address measurement challenges [46]. In August 2015 the Government of the Republic of Zambia started distribution of co-packaged 200 ml ORS and zinc and similar products are becoming available in the private sector through a large supermarket chain. Innovation in product design is an important long-term solution, but there is still a clear need to focus efforts on improving preparation of the more widely available and distributed ORS sachets. At the same time it might make sense to revisit the requirement to boil water.

What mothers want most is a powerful way to stop the diarrhoea that their child is experiencing. As zinc offers this, the curiosity factor may be sufficient to drive initial use of zinc. Zinc trials in several countries have demonstrated that promotion of zinc can enhance ORS uptake and reduce use of antimicrobials and antidiarrhoeals [47–51]. This suggests that zinc has the potential to replace Flagyl™ and other antibiotics as the preferred drug for diarrhoea treatment if awareness increases, the population becomes convinced of its effectiveness and supply is assured.

To our knowledge, ORS preparation has not been observed using video cameras in other settings, an aspect of the research that generated rich data on actual practices and barriers. There is a possibility that filming influenced behaviour and that prior notice of visits to the home caused participants to prepare ORS solution that they would not have otherwise made. Further, clinic recruitment of participants for the behaviour trials may have resulted in a sample that was more receptive to zinc and knowledgeable about ORS than the typical population. The total sample size was small, but data were collected iteratively and there was little heterogeneity in practice or response. If clinic presentation and ORS and zinc use are associated with perceived diarrhoea severity and type of diarrhoea (i.e. diarrhoea not caused by teething) [52], use of ORS and zinc in the wider population may be less common than found here.

Theory has an important role to play in intervention design and evaluation, in particular so that generalisable lessons can be taken from particular contexts [53–56]. The 'Evo-Eco' theoretical framework from the BCD approach proved useful for structuring research methods to investigate hypothesised determinants of these behaviours and to organise study findings. Insights from the formative research will be used to develop an intervention to improve diarrhoea treatment and control following the BCD approach [14].

Ethics approval and consent to participate

Ethical approval for the study was granted by the London School of Hygiene and Tropical Medicine Ethics Board (Ref 6286) and the University of Zambia Biomedical Research Ethics Committee (Ref 012-10-12). Voluntary written informed consent was obtained from all participants, including for the use of video and photos taken during ORS preparation.

Consent for publication

Not applicable.

Availability of data and materials

Given this was a qualitative formative research study, the data consists almost entirely of videos and interview/FGD transcripts and therefore, to ensure participant confidentiality, we cannot make the data available.

Abbreviations

BCD: Behaviour Centred Design; ORS: Oral Rehydration Salts; PAED: Programme for Awareness & Elimination of Diarrhoea.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

KG led the design of the study, carried out data collection, performed analysis and drafted the manuscript. JC participated in the design of the study, carried out data collection and participated in data analysis. VC & RC participated in the design of the study and contributed to data collection and interpretation of the findings. All authors contributed revisions to the manuscript and read and approved the final version.

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Chapter 4: Formative research on handwashing & exclusive breastfeeding

4.1 Overview of chapter

This chapter describes the formative research conducted to study handwashing with soap and exclusive breastfeeding. I first describe the methods specific to the investigation of these behaviours and the rationale for the use of these methods. I subsequently report and discuss the results of the formative research.

4.2 Methods specific to the study of handwashing and breastfeeding

The formative research methods specifically employed to investigate handwashing with soap and exclusive breastfeeding (and thus not described in Research Paper 1) involved household observations with follow-up interviews, handwashing behaviour trials and exclusive breastfeeding focus group discussions. These methods were employed to study current practices, to explore how factors specified in the Evo-Eco theory of behaviour influence current practices and to understand more about social networks and communication channels.

4.2.1 Household video observations

Fifteen mothers of a child under one year-of-age were recruited to study actual handwashing and infant feeding practices. Recruitment was conducted through random walk in the community with the help of Neighbourhood Health Committee volunteers (NHCs) who were well-known and respected by the target population. Trained, female workers carried out direct observation using hand-held video cameras. Observation took place from dawn for a period of four hours. Mothers were informed that the observation was being conducted to understand their daily lives and child-care responsibilities: the target behaviours were not discussed.

Direct observation of actual behaviour is preferable to self-report when resources are available (Ram, 2013, Ram et al., 2014, Biran et al., 2008, Curtis et al., 1993). As in a previous study (Greenland et al., 2013), video observation was found to be acceptable to the study participants. As video footage could be reviewed later, it was also possible to gain a deeper appreciation of the context in which these behaviours were taking place.

4.2.2 Semi-structured interviews

Fifteen semi-structured interviews were carried out with participants the day after household observation in order to understand more about the practices viewed on film and perceptions about the target behaviours. Infant feeding practices in the first year of life (actual or intended, depending on the age of the child) were mapped. The interviews also sought to understand daily routines and social influences on behaviour. Daily routines and the social environment were explored using picture cards to understand how the target behaviours fit into daily life and to identify common points of social interaction and exposure to the health services and mass media (Figure 4-1). Egocentric data on social networks were also collected, along with demographic data, a soap inventory and a spot check of WASH facilities. All interviews were voice recorded.

Figure 4-1. Daily routine captured during interview

4.2.3 Behaviour trials: handwashing with soap

Behaviour trials allow the target population to engage with finding solutions to behavioural problems (Curtis and Kanki, 1998). Caregivers participating in the observation study were purposively recruited for handwashing behaviour trials to further explore drivers and barriers to the practice of handwashing with soap. Four individuals in each study site were selected. As hands were rarely washed with soap during the observation period, it was first important to understand how the physical environment influenced handwashing behaviour. The mother and several of her children were filmed demonstrating how they would wash their hands with soap if they wished to do so. Asking people to demonstrate a given behaviour can be a powerful way of identifying any physical barriers inhibiting practice (Ram, 2013).

In the peri-urban compound, each household was provided with a bar of multi-purpose soap and the primary caregiver was instructed to persuade all family members to wash hands with soap after toilet and before eating. The household was visited at least once within the next 7 days to explore whether the family had managed to wash their hands with soap more frequently at the specified times. The behaviour trials in the rural site were conducted differently as a result of learnings from the peri-urban setting. Each household was provided with a simple handwashing stand and they were requested to ensure soap was always available for handwashing at this location. Experiences were captured a week later. An example of a handwashing stand is shown in Figure 4-2.

Figure 4-2. Handwashing stand with water and soap in rural Ngwerere during the handwashing behaviour trial

4.2.4 Focus group discussion: infant feeding practices

One focus group discussion in both the peri-urban and rural study site was conducted solely to explore social norms and cultural beliefs surrounding infant feeding practices. Groups of up to 10 caregivers with at least one child under two years-of-age were invited by Neighbourhood Health Committee volunteers to participate in these focus groups. The discussions followed a topic guide and included a number of activities to encourage dialogue. Infant feeding practices and key developmental milestones in the first year of life were mapped by month. The map created by the group was used to explore the age that different foods and drinks could be introduced to a child, and to discuss what would happen if food and drink were withheld entirely until a child was six months old. Vignettes - *"short stories about hypothetical characters in specified circumstances, to whose situation the interviewee is invited to respond"* (Finch, 1987) - were used to invite participants to comment on the feeding choices of two fictitious mothers. All focus groups and interviews were voice recorded.

4.2.5 Data handling and analysis

Videos of household observations were reviewed daily, so that any unclear activities could be clarified with the research assistant and so that the behaviours observed could be discussed with the mother during the interview the following day. Videos were subsequently 'parsed' using a template created in MS Excel. This involved reviewing the video and creating a new record in the Excel database to describe each new activity that took place. The record indicated the location of the activity, whether it took place in private or in the presence of others and any objects used to perform it, such as soap. The database was primarily used to explore the frequency of handwashing with soap before or after handwashing occasions related to food handling, defecation or the disposal of child faeces. As the observation only covered a part of the day, it was not possible to use the database to confirm whether an infant was being exclusively breastfed. However, it was possible to establish how, when and what foods were given to infants under six months-of-age. The videos of handwashing demonstrations were reviewed and a short narrative was written to describe the film. Physical factors in the environment that palpably affected the ease of handwashing were identified

during team discussions about the films. This information added context to the data collected through interviews on the determinants of behaviour.

Audio recordings of interviews and focus group discussions were transcribed and translated into English where necessary. The quality of these transcriptions and the translations were verified against the original voice recordings. QSR International's *Nvivo 10* software was used to organise interview and focus group discussion transcripts and to code interview segments following the simple thematic analysis approach described by Braun and Clarke (Braun and Clarke, 2006). This coding was used to identify emergent determinants related to the practice of each of the target behaviours according to the categories of behavioural determinants from the Evo-Eco model (Aunger and Curtis, 2014). The database of parsed video footage was revisited at this time to confirm whether identified factors in the physical and social environment appeared to influence current practices.

4.3 Formative research findings: handwashing and breastfeeding

4.3.1 Characteristics of study participants

Table 4-1 outlines the characteristics of the 15 participants observed and interviewed in peri-urban George and rural Ngwerere to learn more about daily life, infant feeding practices and handwashing with soap. These individuals did not participate in the research on ORS and zinc. Three participants had a child over two years-of-age. The remaining children were all under one year old and eight were six months old or younger. The majority of participants were married homemakers (dependents), although some earned money informally, known as 'piece-work'. The education level in both settings varied, but few women were educated beyond primary school.

Table 4-1. Characteristics of participants involved in video observations and interviews

ID	Age of Mother (years)	HH Size	Age of Children (years / months, or weeks)	Marital Status	Occupation	Husband's Occupation	Mother's Education Level
GEORGE (Peri-urban)							
1	?	6	10yrs, 5yrs, 2yrs 2mo, 5wks	Married	Washes laundry for money	Part-time tyre mending	None
2	37	7	16yrs 14yrs, 8yrs, 5yrs, 4mo	Married	Piece-work (trader)	Unknown	Some primary
3	?	6	8yrs, 6yrs, 3yrs, 7mo	Married	Unemployed	Miller	None
4	27	4	7yrs, 6wks	Married	Unemployed	Businessman	None
5	21	3	2yrs 2mo	Married	Unemployed	Contractor	Completed primary
6	29	10	14yrs, 12yrs, 8yrs, 5yrs, 3yrs, 4mo	Single	Unemployed	NA	Some secondary
7	35	6	12yrs, 10yrs, 2yrs	Married	Piece-work (soap trader)	Truck driver	Some secondary
8	20	10	8yrs, 3yrs, 6mo	Single	Unemployed	NA	Some secondary
NGWERERE (Rural)							
1	?	7	14yrs, 8yrs, 11mo	Single	Unemployed	NA	Completed primary
2	19	3	10mo	Married	Unemployed	Piece-work	Completed secondary
3	44	6	11yrs, 8yrs, 2yrs 2mo	Married	Trader in local beer	Not given	Some primary
4	24	4	4yrs, 6wks	Married	Unemployed	Piece-work	None
5	?	8	15yrs, 14yrs, 9yrs, 5yrs, 1yr 5mo	Single	Piece-work (selling underwear)	NA	Some secondary
6	21	4	2wks	Single	Occasional work (packing)	NA	Some primary
7	22	4	2yrs 9mo, 4mo	Married	Unemployed	Bricklayer	Completed primary

4.3.2 Handwashing with soap practices and determinants

4.3.2.1 Handwashing practices

Video footage revealed that hands were not washed at all in three households and very little handwashing took place in the other 12 households. When handwashing took place, it always took place in a bowl or bucket outside the house, sometimes in soapy dishes or laundry water. Figure 4-3 shows a typical handwashing location. Interviews confirmed these handwashing practices: *"There is some water I put in dishes. This is where we get the water from. Whoever needs to wash their hands scoops some from the dish" (Participant in peri-urban George).*

Figure 4-3. Handwashing location in a peri-urban household showing a bucket with soapy water

Hands were washed when they were dirty from cooking or cleaning, or to remove soap suds from hands after doing laundry or washing dishes. Most food preparation and eating events observed involved porridge, which was prepared and eaten using a spoon. When *nshima* (staple food) was eaten, hands were rinsed with water before and after eating. Interviews confirmed that the practices observed on film were the norm. No handwashing was observed after changing a baby's nappy or after defecation, although latrines were often shared between many households and were not visible from the home, so it was difficult to know when latrine use had occurred.

Soap was used in all but one household during the observation period, but it was only used for handwashing by two women (Table 4-2). One mother washed a child's hands with powder soap before the child ate some bread. She also washed her own hands after disposing of rubbish by hand. The other mother who used soap did so when washing hands that were stained with red floor polish. Soap was available in all households at the time of observation. However, during interview, five households had no soap, four had only powder soap and five had both powder and bar soap. Mothers reported using soap to wash dishes and clothing, and during bathing, but never once spontaneously mentioned handwashing as a possible use of soap. Several households had a bar soap that was solely used for bathing the baby. This supports observation data that soap is not prioritised for handwashing when it is in short supply. Handwashing demonstrations also suggest that

handwashing rarely involves the use of soap as children asked to wash their hands with soap usually asked their mother where to put the soap afterwards. To avoid putting wet soap on the ground they were directed to return the soap to the house, even when their hands were lathered with soap.

Table 4-2 details when and where soap was used in general and for handwashing by the 15 participants in George and Ngwerere who were observed in their homes.

Table 4-2. Observed handwashing occasions and soap use

	Soap available	Observed uses of soap	Occasions when hands were washed	Soap use during handwashing	Handwashing location
GEORGE (Peri-urban)					
HH1	Yes	Dishes	None	NA	NA
HH2	None seen	Not used	Before and after applying cream to children	No	Small dish of water brought by a child on veranda
HH3	Yes	Dishes	Mother washed hands & baby's hands after feeding baby porridge with spoon	No	Small dish on ground outside house
HH4	Yes	Dishes & laundry	Handwashing after polishing floor & after touching charcoal	No, but water appeared soapy	Bucket of water in front of house
HH5	Yes	Dishes	After washing dishes	No, but water was soapy	In dish water
HH6	Yes	Dishes & laundry	None	NA	NA
HH7	Yes	Laundry, handwashing, face washing	After cleaning / before beginning to cook porridge; washed child's hands before child ate bread; after disposing of rubbish with hands; after washing child's face	Yes, except after first occasion	Plastic bowl of existing water (on veranda); face washing in separate bucket (soap dropped in this bucket after use)
HH8	Yes	Handwashing & laundry	After polishing floor	Yes	Bucket of existing water outside house
NGWERERE (Rural)					
HH1	Yes	Dishes & laundry	During cooking, perhaps to wash flour off hands?	No	Bucket of existing water outside house
HH2	Yes	Laundry	Before washing dishes; after doing laundry (rinses soap suds from hands)	No	Dish / laundry water
HH3	Yes	Dishes	While washing dishes; before & after eating nshima (four children)	No	Bucket of existing water outside house
HH4	Yes	Dishes & laundry	Hands rinsed in bucket of water as it was put down; after polishing floor; rinsing laundry suds off hands	No	Bucket of existing water outside house
HH5	Yes	Laundry	During laundry	No, but water was soapy	In laundry water
HH6	Yes	Dishes & laundry	After hanging out laundry; after disposing of rubbish; after doing dishes	No, but water was soapy	In laundry water, bucket of existing water & dish water respectively
HH7	Yes	Laundry	None	NA	NA

4.3.2.2 Factors influencing handwashing with soap behaviour

The possible determinants of current handwashing with soap practices are summarised in Table 4-3. As in Research Paper 1 in Chapter 3, the table is organised by behavioural determinant according to categories specified in the Evo-Eco theory of behaviour (Aunger and Curtis, 2014). Each category is described further in the text below.

Table 4-3. Factors influencing handwashing with soap practices by theoretical construct

Factors in the brain	
Executive *Deliberate planning, knowledge*	People know (and are saturated with) handwashing messages. No planning to buy soap before it runs out – single use sachets of powered soap are purchased as needed for laundry or washing dishes (many people live hand-to-mouth).
Motivated *Emotional drivers, interests, reward*	Hands are washed when dirty, so probably motivated by *disgust* or *comfort*. Soap is harsh on hands. The smell of soap on hands reportedly puts people off their food. Culture of giving away soap during hygiene promotion events is established in the study area. Interventions without giveaways reportedly have low attendance. Soap is desired for laundry above all other things.
Reactive *Cues, habits & skills*	Handwashing is cued by dirt. It is not cued by handwashing stations as there are none. Soap is not habitually used for handwashing (as it is not always available in the household or at the place where it is needed).
Factors in the environment	
Physical *Objects/tools, infrastructure*	Water is fetched daily and availability does not visibly constrain handwashing. Soap is not consistently available in all households throughout the day; single use sachets of powder soap are bought as needed. Latrines are far from the home and are often shared with other households, so it is hard to keep soap and water near the latrine. There is no obvious handwashing place within the home either: hands are washed outside the home, but soap is kept inside the home to keep it clean and 'safe'.
Social *Role models, relationships, networks, norms, institutions*	There does not appear to be a strong social norm governing handwashing with soap after defecation or before handling food, or disgust at those who do not handwash.
Biological *Parasites/foods /animals*	Fear of cholera may temporarily affect handwashing with soap during the rainy season when handwashing is promoted through clinic outreach.

<u>Factors in the brain</u>

Most mothers in interviews and focus groups *knew* that hands should be washed with soap after using the toilet. Some also mentioned that hands should be washed after touching a nappy. Before eating or cooking were not mentioned at all. It is possible that these handwashing occasions have been deliberately pushed to the back of the mind as handwashing with soap is rarely practised at these times. It is also possible that some degree of saturation has been reached by messaging on

handwashing with soap: a key informant clinic worker described that people feel that they know the messages, as they have heard them so many times. Messages on handwashing have also filtered through from door-to-door health visits and via the radio. According to a clinic worker, hygiene promotion events that do not give out soap are poorly-attended.

Handwashing was *motivated* by visible dirt on hands to facilitate the removal of stains and odours, such as the red polish that is applied daily to floors and doorsteps. As soap is promoted during cholera outbreaks and knowledge about cholera was high, soap use during handwashing may not be considered important on a day-to-day basis. Handwashing with soap before eating was inhibited by the smell of soap, which reportedly affects the taste of the food.

Factors in the environment

Even if someone desired to wash hands with soap after returning from the toilet, there were no obvious cues in the environment to remind them to do so. Furthermore, handwashing with soap was logistically difficult, as the toilet, water and soap were all located in different places. Figure 4-4 summarises the typical actions that a person needed to take to wash their hands with soap after defecation. This schematic is based on observed barriers to handwashing on video footage and during handwashing demonstrations and remarks made during interviews and handwashing trials.

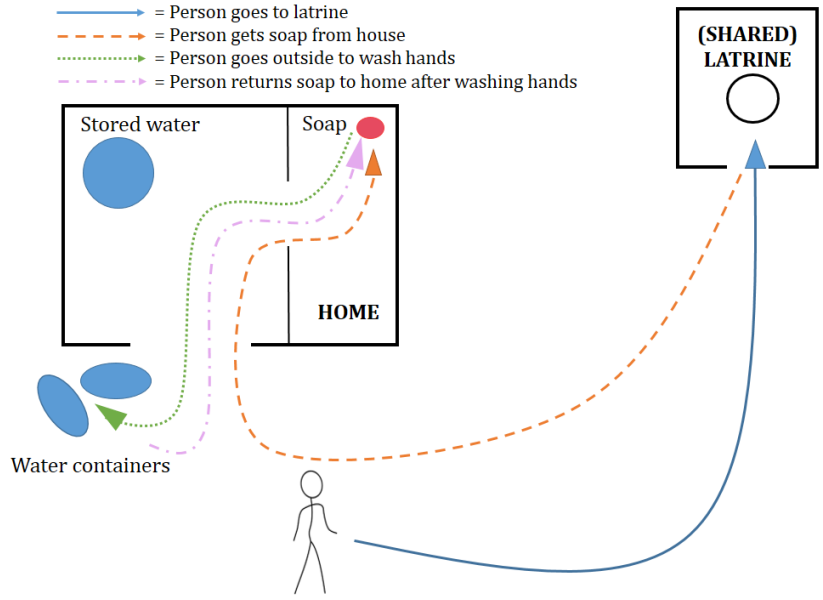

Figure 4-4. Schematic to illustrate the logistical difficulties associated with handwashing with soap after toilet use

Handwashing trials in rural Ngwerere tested simple handwashing stands to try to improve the co-location of soap and water for handwashing. Participants were concerned that bar soap would be stolen and elected to keep powder soap at the handwashing place: this soap was washed away by rain. The small size of the supplied water containers meant that someone in the household needed to constantly refill these containers. One neighbour decided to build their own handwashing stand, but it is not possible to know whether this initial envy resulted in improved handwashing behaviour.

Participants freely admitted that they did not use soap when they washed their hands before eating, and they did not always use soap for handwashing after defecation:

> *"Sometimes I do wash my hands with soap [after using the toilet]; other times I wash them with plain water."* (Participant from Ngwerere)

This suggests that handwashing with soap is not a *social norm* and that those who fail to wash hands are not disapproved of.

Participants associated washing hands for the sake of handwashing with the avoidance of cholera. This was unsurprising given the extent of cholera messaging observed on posters and walls in clinics and the communities.

4.3.3 Exclusive breastfeeding practices and determinants

4.3.3.1 Exclusive breastfeeding practices

Two of eight mothers in George and four of seven mothers in Ngwerere reported either that they had exclusively breastfed their child for six months or that they intended to do so. The majority of mothers admitted introducing – or planning to introduce - other liquids and foods before six months. Porridge was generally the first food that was introduced, although one mother gave bean soup almost from birth. Porridge was either made from maize and groundnuts (following clinic advice), or was shop-bought. Brands such as *Cerelac* were considered safer than thick, home-made porridge. Introduction of the family food of *nshima* was uncommon before six months-of-age.

Figure 4-5 outlines the actual and planned infant feeding practices reported by 15 mothers in peri-urban George and rural Ngwerere during the first year of their youngest child's life. Snack foods and thick shop-bought drinks made from maize-meal and milk such as *Maheu* and *Super Shake* were also observed to be given to infants 0-5 months old, but these items were not always reported.

ID	Age of mother	Age of child	Planned (white) and actual (black) feeding practice during first year of life 0 1mo 2mo 3mo 4mo 5mo 6mo 7mo 8mo 9mo 10mo 11mo 1yr
GEORGE (Peri-urban)			
1	?	5 weeks	Bean soup & breast milk; Bean soup & breast milk; Porridge /yoghurt; Kapenta & porridge; Nshima (family food)
2	37	4 months	Breast milk only; Porridge, Super shake; Unknown
3	?	7 months	Breast milk only; Porridge, Nshima; Porridge, Nshima
4	27	6 weeks	Breast milk only; Breast milk only; Porridge; Unknown
5	21	2 years 2 months	Breast milk only; Porridge; Nshima
6	19	4 months	Breast milk only; Breast milk only; Porridge; Unknown
7	35	2 years	Breast milk only; Porridge & formula milk; Nshima
8	20	6 months	Breast milk only; Super shake; Nshima
NGWERERE (Rural)			
1	18	11 months	Breast milk only; Porridge; Nshima & maize drinks
2	19	10 months	Breast milk only; Porridge & nshima; Nshima
3	44	2 years 2 months	Breast milk only; Nshima
4	24	6 weeks	Breast milk only; Breast milk only; Porridge first, nshima later
5	23	1 year 5 months	Breast milk only; Porridge & Maheu, child refused porridge a lot; as was difficult tried nshima
6	21	2 weeks	Breast milk only; Breast milk only; Unknown
7	22	4 months	Breast milk only; Breast milk only; Porridge; Nshima

Figure 4-5. Reported and planned infant feeding practices in first year of life

4.3.3.2 Factors influencing exclusive breastfeeding behaviour

The possible determinants of decisions on the duration of exclusive breastfeeding are summarised in Table 4-4. The table is organised by behavioural determinant according to categories specified in the Evo-Eco theory of behaviour (Aunger and Curtis, 2014). The findings related to each category emerged from the thematic analysis of data from interviews and focus groups. Each category is described further in the text below.

Table 4-4. Factors influencing exclusive breastfeeding practices by theoretical construct

Factors in the brain	
Executive *Deliberate planning, knowledge*	Mothers know how long they should exclusive breastfeed for and why – practice is not driven by lack of knowledge (although there is confusion over messaging for HIV-positive mothers). Women believe that women who exclusively breastfeed for six months are likely to do so because they are HIV-positive. Many traditional beliefs surround breastfeeding: for example, that a child will become damaged if you continue to breastfeed when you become pregnant.
Motivated *Emotional drivers, interests, reward*	All motives seem to point against exclusive breastfeeding: it is seen as something the poor do (*status);* it affects appearance of breasts and milk smells (*attraction);* it hurts when a child sucks too much, or a woman has sores (*comfort);* it is starving your child when they are hungry (*nurture)* – although this is also a strong motive for breastfeeding in general. The main *nurture* aim is to create a fat (= healthy) child that is envied *(status)* by others. The best way of doing this is to give food.
Reactive *Cues, habits & skills*	Breastfeeding is on demand but is also cued by crying or to put child to sleep. Giving food can be a response to crying (desire to stop the crying – and it works) or cued by a child's developmental stage (e.g. when a child sits up / crawls).
Factors in the environment	
Physical *Objects/tools, infrastructure*	Attractively packaged, cheap snack drinks that look like milk are readily available.
Social *Role models, relationships, networks, norms, institutions*	There are no good role models – the perception is that nurses give them a 'rule' but don't follow it themselves. Family and friends have many contrasting opinions on what and when to feed a child. For example, older relatives say they fed in some particular way and they were fine. Experiences with other children are also important. The social norm is to give porridge and other drinks to children before 6 months – it is not shocking or considered wrong. These items are not perceived as food or considered to be harmful in same way as nshima (which is not given to very young children).
Biological *Parasites/foods /animals*	Breast milk is free and may influence feeding practices in poorer households. Mothers report that their milk is low quality or insufficient to placate their child. Family food is available to be given to the child.

Factors in the brain

Mothers interviewed and attending focus group discussions all knew that they should exclusively breastfeed an infant during the first six months of their life. They could also list multiple benefits of (exclusive) breastfeeding, including the prevention of illness and transfer of important nutrients to the child. In addition, they were almost unanimous in the opinion that giving a young baby food could damage their *"soft"* intestines. The disconnect between what is believed and how infants are actually fed can be partly explained by people's perceptions of what constitutes food. The advice on exclusive breastfeeding was not seen to apply to maize and milk-based drinks. Porridge (especially shop-bought brands) was

similarly discounted, as it is thin and easy to digest and therefore not considered a real food like *nshima*. The following quotes illustrate these points:

> *"The reason why we started giving him super shake [drink]? He does not breast feed a lot and at times he refuses breast milk. While we were waiting to introduce porridge at 6 months we started giving super shake."* (Participant from George)

> *"I realized that the porridge has no power in the body and in the intestines, Nshima give energy, porridge is like water."* (Participant from Ngwerere)

The decision to introduce liquids and foods before six months was also influenced by the mother's body and health. Women reported that they felt that their milk was of low quality because they themselves did not eat well (as advised in the clinic). Physical discomfort also prevented them from (exclusive) breastfeeding. A woman's HIV-status may also influence her feeding choices. According to focus group participants, a mother's HIV status could be determined by how she feeds her child.

The desire to have a fat baby seemed to be a strong *motivation* for the early introduction of solid foods. Fat babies were seen to be healthy *(nurture motive)* and envied by other mothers *(status motive):*

> *"Since my baby is fat, most of my friends ask me what I feed my child on".... I change the food if she has put on weight. I want to know whether the food I feed my child is good for her growth."* (Participant from Ngwerere)

Focus group participants also said that husbands often discourage breastfeeding because they do not like the smell of milk (*disgust motive*). The child's behaviour also *cued* the introduction of other foods and liquids. For example, reaching a milestone such as crawling prompted the need to introduce solid foods, while a child that was crying a lot was believed to be hungry and only satisfied by food.

<u>Factors in the environment</u>

Social influences appeared to be an important determinant of infant feeding practices. Women felt that exclusive breastfeeding was a *"rule"* that was designed for the poor, but that others, particularly nurses at the clinics who gave them this

advice, did not follow this guidance themselves. Older female family members and neighbours were another important source of advice and information. The following quote from the focus group in George compound is illustrative of the many comments made concerning other people's opinions on how they should feed their baby:

> *"My sister forces me to start feeding my baby at 3 months …."*

However, it was unclear whether women felt able to advise their friends and neighbours on how to feed their children. In the words of one woman from George, such advice could be offensive because it *"might not be her plan for her child".*

Experiences with previous children also influenced current practices, as demonstrated by the following quote:

> *"I always get sores on my nipples when breast feeding so I stop at four months, it's like this with all my children …."* (Participant from George).

4.4 Discussion of handwashing and exclusive breastfeeding findings

The formative research succeeded in shedding light on actual handwashing and infant feeding practices in the target population. It also uncovered factors that were likely to be important influencers of these practices.

Handwashing in general was rare, occurring in association with tasks that made hands visibly dirty. Soap was almost never used when hands were washed. Hands were never washed with soap before eating. It is interesting to note that studies elsewhere that have succeeded in improving handwashing after defecation have often failed to change handwashing habits before eating (Huda et al., 2012, Scott et al., 2008). It is likely that handwashing at this time is governed by factors different from handwashing after defecation (Scott et al., 2007, Aunger et al., 2010). This implies that it may not be appropriate to promote handwashing on many occasions. Nor may it even be feasible to request this of caregivers (Luby et al., 2011).

Soap was available in households during observation, but was not always found in the same households during interview the following day. It is likely that this disparity was caused by the different timing of these two activities. Interviews took place later in the day than video observation, by which time single use soap sachets had already been purchased and used for laundry and washing dishes. Furthermore, when soap was available it was kept inside the house to keep it clean and safe. Collectively, these findings suggest that soap is viewed to be a precious commodity and handwashing wastes it. Once again, this finding is not unique to our study (Aunger et al., 2010). These observations, coupled with possible 'programmatic fatigue' in the target population, indicate that there is a clear need to find a novel way to attach new meaning to handwashing. It may be possible to achieve this through the manipulation of emotional drivers such as *disgust* and *nurture* (Curtis et al., 2011, Biran et al., 2014, Aunger and Curtis, 2013).

The fact that soap was kept inside and latrines were often shared and outside a familial compound made it cumbersome to wash hands with soap after defecation. Handwashing stands offered a designated handwashing location and opportunity to co-locate water and soap, but a solution was not found to ensure that soap and water were put at this handwashing place. Studies elsewhere have shown that the presence of handwashing facilities is an important predictor of handwashing (Dreibelbis et al., 2013, Hulland et al., 2013, Luby et al., 2009b, Aunger et al., 2010) and may help in the formation of new handwashing habits (Neal et al., 2015). Nevertheless, provision of infrastructure alone is not always well correlated with handwashing practices (Luby et al., 2009a, Ram et al., 2014). Indeed, handwashing levels in high-income countries with adequate facilities are far from optimal (Freeman et al., 2014). Cheap, simple, robust, easily-maintained and available technologies to facilitate handwashing with soap remain to be developed.

Caregivers were well-informed about exclusive breastfeeding and all knew that mothers should breastfeed exclusively for the first six months of a child's life. Nevertheless, it was common to introduce porridge and maize-based drinks to infants before six months of age. However, women were not overly forthcoming about whether they themselves had deviated from the – in their words – *"rules"* concerning exclusive breastfeeding, suggesting that it is a socially desirable behaviour. As commonly seen in studies of breastfeeding behaviour (Menon et al.,

2002, Dennis et al., 2012, Doherty et al., 2012, Johnson et al., 2012, Meedya et al., 2010), infant feeding choices were strongly influenced by older family members and experiences with a previous child. An intervention that does not address the importance of social influences and actual norms may have limited ability to change behaviour (Briscoe and Aboud, 2012).

Conflicting opinions were offered on whether and how an HIV-positive mother should breastfeed and whether or not breastfeeding alone is sufficient to meet a child's needs and produce a healthy, fat baby. In 2010, WHO recommended that all infants, regardless of maternal HIV status, should be exclusively breastfed for the first six months of life (WHO, 2010). This policy marked a shift from previous recommendations to counsel HIV-positive mothers on the available feeding options (WHO, 2003). It is therefore likely that health workers have promoted mixed messages, which has caused confusion and distrust, particularly as Zambians are well-informed about the risks of transmission of HIV via breastmilk (Central Statistical Office [Zambia] et al., 2014). Although any breastfeeding promotion intervention should promote a universal message to all mothers, it is likely that maternal HIV status will influence intervention uptake in this population. The cultural belief that a fat baby is a healthy baby and that this cannot be achieved through breast milk alone is not unique to this setting (Arts et al., 2011, Thomas and DeSantis, 1995). However, shifting ingrained cultural beliefs steeped in tradition is a challenge for a behaviour change intervention (Aboud and Singla, 2012).

Other common reasons that emerged as potentially important determinants of the duration of exclusive breastfeeding – insufficient (quality of) milk, physical discomfort, crying and hungry babies reaching particular developmental milestones - are supported by other studies in Zambia (Chisenga et al., 2005, Chisenga et al., 2011, Fjeld et al., 2008) and the wider breastfeeding literature (Loughlin et al., 1985, de Jager et al., 2013, Thulier and Mercer, 2009, O'Brien et al., 2009). However, one main difference was observed: in many settings, women cease to breastfeed exclusively when they return to work (Doherty et al., 2012). This was not a barrier to breastfeeding in this population, as few women were employed in the formal sector.

The formative research identified a number of potentially modifiable influences on handwashing with soap and infant feeding practices in the first six months of life. However, potential bias introduced by the research methods should be considered when interpreting these findings. Research assistants suspected that a number of participants did not carry out their normal activities during the observation period. However, some level of reactivity is to be expected in any study of behaviour (Biran et al., 2009, Ram et al., 2010, McCambridge et al., 2014, Cousens et al., 1996). As the purpose of the study was not communicated to participants in advance, it is unlikely that reactivity would have affected data collected on the target behaviours. It is also possible that mothers did not respond honestly to questions on handwashing and infant feeding practices during interviews – intentionally or due to an inability to introspect -, or that the questions did not accurately uncover behavioural determinants.

Rich, context-specific information on actual practice of the target behaviours obtained in this study was previously unavailable and was invaluable in the development of a tailored, multiple behaviour change intervention. The following chapter focuses on the design of the resulting intervention and describes the important contribution of the formative research findings to this process.

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Chapter 5: Intervention design

5.1 Overview of chapter

While it is increasingly common to read that interventions have been "*informed by formative research"*, few investigators fully describe the content of their interventions (Michie et al., 2009, Abraham et al., 2014) and information on the intervention design process is almost never reported (Young et al., 2006). In this chapter I describe the development of the *Komboni Housewives* intervention. The components of the intervention are described in relation to the underlying intervention theory and the theory of change for the intervention is provided.

5.2 Overview of creative process

As with the formative research, the creative process followed the intervention design steps of the Behaviour Centred Design approach (Aunger and Curtis, 2016).

Formative research findings were shared with key stakeholders from the Government of Zambia, civil society and other Zambian organisations working on these behaviours in a dissemination meeting held in June 2013 in Lusaka. The project team subsequently distilled the most pertinent findings into a 'creative brief'. This brief was used to solicit applications from creative agencies interested in developing the intervention content.

The initial agency recruited did not engage well enough with the brief after two reverts and they were replaced in September 2013 by the Zambian branch of worldwide advertising agency *DDB. DDB Iris* was briefed in person on the target behaviours and the 'Evo-Eco' theory underlying the Behaviour Centred Design Approach to intervention development (Aunger and Curtis, 2016). Under close supervision from CIDRZ and LSHTM, *DDB Iris* worked through a series of iterations to develop the intervention concept and full campaign. The intervention's theory of change was developed in parallel to ensure that all included intervention activities were based on hypotheses about how change in the target behaviours would be

brought about. The campaign concept and individual intervention components were refined, based on feedback from the target population. The final intervention package was ready for roll-out by March 2014 and the intervention was delivered over the following six months.

In the following sections, I will detail the procedures undertaken to develop the creative materials.

5.2.1 Briefing the creative agency

A creative brief is a tool used in the commercial sector to guide design of communication campaigns. The creative brief provided to *DDB Iris* presented a set of clear instructions on the behavioural tasks and provided detailed background on the target behaviours based on the formative research findings described in Chapters 3-4. The creative brief was shared with the Creative Agency in a small workshop to ensure that everyone understood the purpose of the brief and the principles of Evo-Eco Theory (Aunger and Curtis, 2014) and Behaviour Centred Design (Aunger and Curtis, 2016). Besides providing information on the target behaviour, the brief also included additional findings related to the daily lives of the target population and a list of intervention design principles to maximise the potential of developing a scalable, effective intervention appropriate for use in rural and peri-urban communities with low literacy levels. The importance of developing an intervention that coherently united the target behaviours without conflicting with or discrediting existing public health messaging was also emphasised.

Table 5-1 summarises the key insights from the formative research that were included in the creative brief and elaborated on in the workshop. The full, 7-page brief can be viewed in Appendix A.

Table 5-1. Summary of the main content of the creative brief

Target behaviours
• Timely use of correctly mixed and administered oral rehydration salts (ORS) with Zinc[1] for diarrhoea among the under-fives • Handwashing with soap (HWWS) at home after using the toilet or cleaning up a child's faeces; and before preparing food, eating, or feeding a child (the latter food-related times TBD) • Exclusive breastfeeding (EBF), which means not giving the child other liquids or foods of *any* sort, up until 6 months-of-age
Background on target behaviours
• Handwashing with soap is rare, especially at key times (after defecation etc.). People will say they've heard about washing hands after the toilet and most will say that in this moment, if they do it, they use soap. Water is readily available in buckets outside the home. Soap (i.e. powder, paste, or bar) often runs out in the course of a day and is kept inside when not in use. • Mothers know that women *should* exclusively breastfeed until their baby is six months-of-age, but consider this a "rule for the poor" (i.e. currently associated with low *status*). In reality, most mothers gradually introduce food (e.g. porridge) and liquids (e.g. *Maheu*) as early as one to two months after birth. These items are not always recognised to be 'foods'. Infant feeding choices are influenced by husbands, grandmothers and female neighbours, but are also a response to a baby's perceived needs (interested in food, crying due to hunger), or a mother's HIV status or perceptions about the quality of her milk. • ORS is a known diarrhoea treatment and believed to give the child 'energy'. ORS may be given if present in the home (or borrowed from a neighbour), but it is frequently sub-optimally prepared and administered (not continuously enough). ORS may also be prepared after a clinic visit. • There is some very low-level awareness that Zinc is a diarrhoea medicine – and all study participants were interested in it (as they seek *medicine* to stop diarrhoea), but it is not commonly available. Zinc should be prescribed at clinics, but, as supply is limited, prescriptions are not always written.
Other relevant information
• Life is lived and children are raised across many households: *"your neighbour's child is your child"* philosophy: People are poor and resources and household items are shared / borrowed as needed. Medicines may be hoarded and used to treat future ailments. Visiting friends and relatives is part of daily life, as is sharing information and knowledge. In compounds, houses are mostly rented and one lives largely communally, under the eye of neighbours. Tenure is precarious and people move house a lot. When they move to a new neighbourhood it takes time to learn where things are. • Status matters: having a child brings status: a well-looked after child (i.e. "a healthy child is a fat child") confers status through competency as a mother. Information as social currency brings or maintains status. Clinic-workers have status but can abuse it and are not always respected. Neighbourhood Health Committee volunteers (NHCs) are generally admired and respected. • Responding to the child - their state, energy levels, requests, their rebuttals, likes and dislikes - is one way mothers explain how they work out how to nurture children: e.g. when my child cries after breastfeeding – surely s/he is asking for other foods? When my child's energy returns - surely it's time to stop giving them ORS? When they look better – surely they are better?
Key behaviour change tasks
• Address 'for the poor' low <u>status</u> image of breastfeeding. • Make EBF feel doable by re-expressing timeframes – e.g. 'every extra day' vs. 'for 6 months'. • Make soap something households don't run out of. • Have a <u>designated place</u> for handwashing with soap next to water outside the home. • Make washing hands with soap (before food) and after the toilet good manners, underpinned by *disgust.* • Make third loose stool call to action to give ORS <u>now</u> and get to the clinic <u>asap</u> for zinc by tapping into women's desire to respond to their child's needs – e.g. 'one thing your child *can't* tell you ….' • Key (missing) behaviours around Zinc + ORS practised: ORS diluted to right volume; ORS given continually until diarrhoea stops; Zinc once a day for 10 days.

1 Zinc is largely unavailable in Lusaka Province. Ensuring continuity of supply and access will be essential.

The creative agency's first task was to use the information from the creative brief to develop an overarching 'Big Idea' to unite the behaviours without focussing on health or diarrhoea (considered to be too close to standard health education tactics, which have proven ineffective as previously described).

5.2.2 Concept development: the 'Big Idea'

Other than their importance in diarrhoea control, handwashing with soap, exclusive breastfeeding and use of ORS and zinc are unrelated. They also take place in different situations during the day and at different stages in a child's life. To deliver a coherent, consistent campaign, we first sought to identify a way of connecting the behaviours under a common theme, or brand. We began by reviewing the factors hypothesised to motivate practice of each of the target behaviours, in search of a common driver of behaviour. Human behaviour is in part determined by 15 motives – internally triggered drives, environmentally stimulated emotions, and interests - that evolved to help us perform functions that aid survival or reproduction (Aunger and Curtis, 2013, Aunger and Curtis, 2015). The 15 human motives and their purposes are listed in Table 5-2.

Table 5-2. The 15 human motives, modified from (Aunger and Curtis, 2013)

Motive	Purpose	Example tactics
Lust	Mate	Select/court mate, copulate
Hunger	Acquire resources	Eat, drink, forage/hunt
Comfort	Maintain body	Seek air/sun, relocate to dry/warm conditions, wear clothes, tend wound, self-medicate, sick-role behaviour, rest/sleep, excrete
Fear	Avoid hurt-from without threats (predation)	Aggregate in large group, stay close to kin, stay far from predator habitats, freeze/flight/ fight, avoid accidents
Disgust	Avoid hurt-from within threats (parasitisation)	Avoid parasites, infected others, animal vectors, and contaminated environments
Attract	Acquire high quality sexual relationships	Adorn, self-groom, body-building/modification, acquire high-quality territory, make high-quality nest
Love	Maintain relationships	Maintain/defend pair-bond, (e.g. guard), elicit investment (e.g. cry)
Nurture	Rear offspring/aid dependent kin	Give resources, protect from dangers, provide opportunities for play, transmit status, nepotism
Hoard	Accumulate/defend consumable resources	Acquire territory, cultivate, threaten/coerce/ forcibly take resources of others, exchange, contract, collaborate; guard surplus resources
Create	Improve habitat	Migrate, build, improve/order/clean habitat/ territory; remove/destroy predator habitats, remove holes; remove/destroy pathogen habitat
Affiliate	Affiliate with groups	Cooperate, conform, participate in group, display panic, display intent to cooperate/reciprocate, share knowledge (e.g. gossip), seek alliances
Status	Invest in status improvement	Derogate competitors, submit to/flatter superiors, form coalitions, accumulate tradable resources, display awareness of social error/taste
Justice	Maintain functioning of large non-kin groups	Punish/shun free-riders/cheaters, engage in/reward selfless behaviour, preserve environment for future
Play	Acquire knowledge about the world	Wander, roam, observe, seek to understand/explain, manipulate (novel) objects, consume symbolic information (e.g. read)
Curiosity	Acquire/increase/hone skills	Invest in practice behaviour/skills (e.g. sport, poetry, music, conversation), observe/imitate

The notion that associating practice or avoidance of a given behaviour with a (new) motive may drive behaviour change in an enabling environment forms the basis for interventions designed using the Behaviour Centred Design approach (Aunger and Curtis, 2016), including the successful SuperAmma handwashing campaign in rural India (Biran et al., 2014).

Following the creative brief, *DDB Iris* reviewed the motivated drivers of behaviour, identified by the formative research, and conceived a campaign based on *nurture*, the motive to rear offspring (Aunger and Curtis, 2013) (Figure 5-1). The central theme of the idea was the promise that children would never die of neglect again, exemplified by 'Maluba' (meaning flower in the vernacular - Nyanja), a 2-year-old neglected and wasted girl who needed to be nurtured back to health.

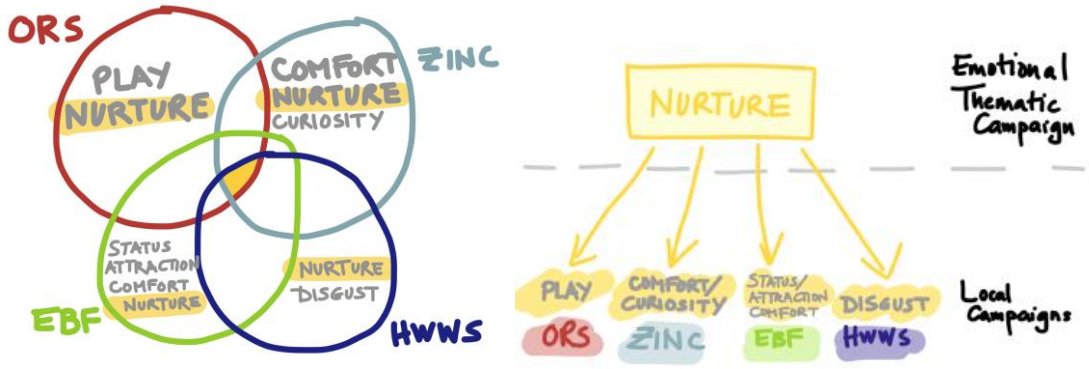


Figure 5-1. The first campaign concept, centred around the nurture motive, from DDB Iris

The concept was rejected by the project team on several grounds: i) the neglect tone was too negative and the disconnect between Maluba and the lives of the target population would be unlikely to inspire change based on nurture; ii) this type of rhetoric was still based on health messaging; and iii) it was difficult to visualise how the concept would translate to behaviour change for each of the target behaviours.

The formative research revealed that many activities take place outside in full view of neighbours, and mothers were eager to avoid being a source of gossip in their community. The creative agency was therefore re-briefed and asked to develop another 'big idea' for the intervention based on the pro-social motive of *affiliation,* the drive to become and remain an accepted member of a given social group (Aunger and Curtis, 2013). The goal was to create the impression that other people

notice your behaviour and that carrying out the target behaviours would lead to social approval.

The agency came up with the concept of 'Good Neighbours', which quickly evolved into 'Neighbours are talking' and women who did not perform the target behaviours might become the subject of gossip. For example, the message for ORS implied that neighbours would comment about a mother who did not know how to prepare ORS solution correctly. The concept was tested in focus groups with the target population in both slum and rural settings. The target audience felt that a neighbour who gossiped was not a good person and was not someone whose advice should be listened to. The concept was revised and the *Adzimayi Bamu Komboni,* or *Komboni Housewives* were born.

Komboni is the word used to describe women living in peri-urban areas, but rural women also identified with and aspired to this status. The *Komboni Housewives* were a group of six women (personified by actors and cartoon characters) who gossiped about their neighbours, suspecting that they did not practise the target behaviours. They were then subsequently proven wrong in this assumption and welcomed their neighbours into their social circle. The campaign aimed to instigate new normative beliefs and practices by creating the impression that the target behaviours were already a social norm (Berkowitz, 2004). The tagline 'Tiku cheking'ani' means 'We are watching you'.

Figure 5-2 shows a poster to illustrate the Good Neighbours concept and the final *Komboni Housewives* campaign idea.

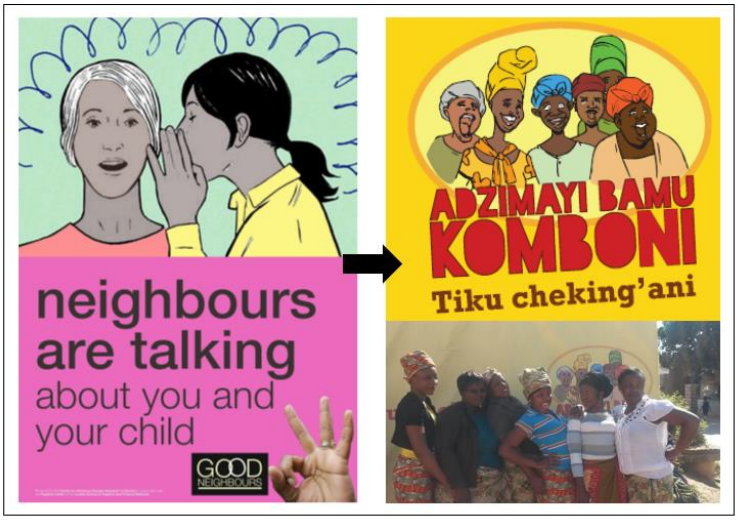


Figure 5-2. Evolution of the Good Neighbours concept into the final campaign idea

5.2.3 Intervention components

With this central idea in hand, *DDB Iris* developed a number of components for the campaign, including radio adverts and call-in programmes on local radio stations and three face-to-face intervention components:

1. Women's forums held in households in the community with caregivers of children under-five animated by *Komboni Housewife* characters;
2. Oral Rehydration Therapy (ORT) corner sessions held at health clinics with caregivers of children under-five, supported by monthly prize draws attended by the *Komboni Housewives*;
3. Road shows delivered in public gathering spaces in the community animated by the *Komboni Housewives* with the aid of a local celebrity singer (*Afunika*).

We hoped that use of multiple delivery channels would allow us to reach a greater number of individuals, increase message resonance and increase the dose delivered to each individual. Women's forums were small, intensive interpersonal events. ORT corner sessions were intended to serve a similar purpose in a different setting, while road shows and the radio element of the campaign intended to raise awareness of the intervention and sensitise the community.

Images of the delivery channels used in the face-to-face intervention components are shown in Figure 5-3.

Figure 5-3. Intervention activities took place in women's forums (left), clinic sessions (middle) and at road shows (right)

Intervention delivery was coordinated by an activation agency, *EXP*. *EXP* was charged with the recruitment of actors to take on the roles of the *Komboni Housewives*. These women facilitated the forums and road shows. The ORT corner sessions at the clinics were delivered by two NHCs linked to the clinic in each site. Using the NHCs who were already known and respected in the community helped to legitimise the campaign. It also made use of the existing structure for community outreach. The activities of the NHCs were supervised directly by CIDRZ, while *EXP* provided them with supplies and intervention materials. Incentivised DJs played radio adverts on the target behaviours and ran the radio shows that featured the target behaviours and linked with the forums.

5.2.4 Intervention content

Radio advertisements, comical skits and films were used to imply that the behaviour of non-conformers is noticed and gossiped about, and that this leads to social rejection. The intervention also drew on the *disgust* motive, a recognised strong driver of hygiene behaviours (Curtis and Biran, 2001). An interactive 'Shit and Shake' activity used in the community-led total sanitation approach (Sigler et al., 2015) sought to heighten disgust associated with not washing hands with soap after toilet use. As infants may be given other liquids and foods alongside breastmilk from 2-3 months-of-age, *disgust* was also used to encourage exclusive breastfeeding of infants up to six months-of-age through graphic portrayal of the contents of the stomach of a mixed-fed baby. This activity also aimed to evoke the *nurturing* instinct to cause mothers to think twice before mixed-feeding their young infants. We have since dubbed such emotional demonstrations 'emo-demos'.

The behavioural task for ORS was two-fold: caregivers needed to attach more value to the use of ORS during diarrhoeal episodes and they needed to learn how to prepare ORS solution correctly (given the formative research findings of poor practice). Interactive skill-based demonstrations based on the *nurture* motive were used to convey the functional benefits of administering correctly prepared ORS, while skill-based knowledge on ORS preparation was boosted through demonstration and behaviour modelling, utilising several behaviour change techniques (Michie et al., 2015, Briscoe and Aboud, 2012). The intervention

activities involving ORS were also used to raise awareness of zinc and to increase demand for the use of zinc for diarrhoea treatment.

Figure 5-4 shows the disgust-based emo-demos used to target handwashing with soap and exclusive breastfeeding, and the skill-based demonstration used to improve caregiver ability to prepare ORS solution.

Figure 5-4. Emotional and skill-based demonstrations used in the Komboni Housewives intervention

Intervention content was developed deliberately and iteratively through a series of rounds of piloting and revision. For example, the below extract comes from a report written by the creative agency following pre-testing of the films used in the intervention. The specific comments relate to feedback provided by the target population in relation to the proposed film on exclusive breastfeeding.

> *There are some obvious areas where the film departs from what's normal among Zambian women when they're in conference socially. The ladies aren't sitting properly, this has come up a lot, and sitting in an empty living room implies they are at a funeral. The lady in the other room also poses too big a mystery to be ignored - why is she sitting by herself when everybody's (here) rejoicing over the newborn baby? There is also something incorrect about the mother's breastfeeding posture, which if I recall correctly has to do with the angle at which she is not holding the baby's head in relation to her breast. We could explore an (outdoor) background, with the ladies sat on a mat and with their legs stretched out in the more regular sitting position.*

These factors were corrected in later iterations of the films, which were similar in content to the skits acted out in the forums and road shows. The final script and select storyboard images for the exclusive breastfeeding film are presented in Figure 5-5.

Figure 5-5. Select exerts and storyboard images from the exclusive breastfeeding film

An overview of the content of the *Komboni Housewives* intervention can be found in Table 5-3. Further information on the intervention, including the campaign manual, is available at: http://kombonihousewives.lshtm.ac.uk/.

Table 5-3. Overview of Intervention Content and Delivery Schedule

Component	Audience	Setting	Implementers	Content	Timing
Radio adverts & Call-in Show	Population in target areas, particularly caregivers of children under-five	Broadcast on Komboni FM, Radio 1 and Radio 4	*Komboni Housewives* and Radio Master of Ceremonies (MCs)	Airing of three different spot adverts (EBF, HWWS, ORS+Zinc) with similar content to that described in the forum & road shows skits. Call-in shows used as a discussion forum and to amplify the activities of the women's forums (the timing of the shows coincided with the women's forums). Discussions scripted around the target behaviours to test the callers' understanding of the intervention messages. Campaign 'jingle'.	3 times a week for six months, with penetration in both intervention and control areas.
***Komboni Housewives* Women's Forums**	~20 caregivers of children under-five per forum	Forums held in the community at the home of a host (an intervention recipient)	*Komboni Housewives*	All four behaviours targeted using: 1) skits (featuring the *Komboni Housewives* gossiping about mothers they believe are not practising the correct behaviours, being proven wrong and welcoming the mother into their group); 2) discussion with question and answer sessions; 3) emotionally engaging demonstrations (designed to evoke feelings of disgust at mixed feeding a baby under six months and not handwashing with soap, and nurture in relation to incorrect preparation of ORS); and 4) short films featuring the *Komboni Housewives* (introduced partway through the intervention period). Activities were supported by banners, certificates, stickers, a branded bus and prizes (hats and T-shirts).	One or two forums a day depending on the setting throughout the intervention period; rotated between the eight intervention areas
Clinic ORT Corner sessions (with monthly prize draw)	Caregivers of children under five (preferentially those with a child presenting with diarrhoea)	At the ORT corner (where ORS is traditionally available) or other designated area in the clinic	Two Neighbourhood Health Committee Volunteers (NHCs) linked to clinic in each site	Circle of Mothers: content similar to forums designed to be shorter and focussed on exclusive breastfeeding and ORS and zinc. Prize draws: Winner of a hamper selected from all caregivers who attended the clinic session in the previous month. The *Komboni Housewives* conducted a mini forum at select prize draws.	Every Monday-Friday during busy periods at clinics in all 8 sites One per month in each site. Attended by *Komboni Housewives* once per site.
Roadshows	All community members	Large public space in each site	MCs, *Komboni Housewives* & *Afunika* (local musician)	Large events in each intervention area. Similar content to the forums but energised by the presence of the MCs and a famous Zambian musician *Afunika,* who sang the campaign song, engaged the audience in discussion about the target behaviours. CDs featuring the campaign song as well as hat and T-shirts were given as prizes for correct answers.	One road show in each site

KEY: MC = Master of Ceremonies; EBF = exclusive breastfeeding; HWWS = handwashing with soap; ORS = oral rehydration salts; ORT = oral rehydration therapy

5.3 Intervention theory of change

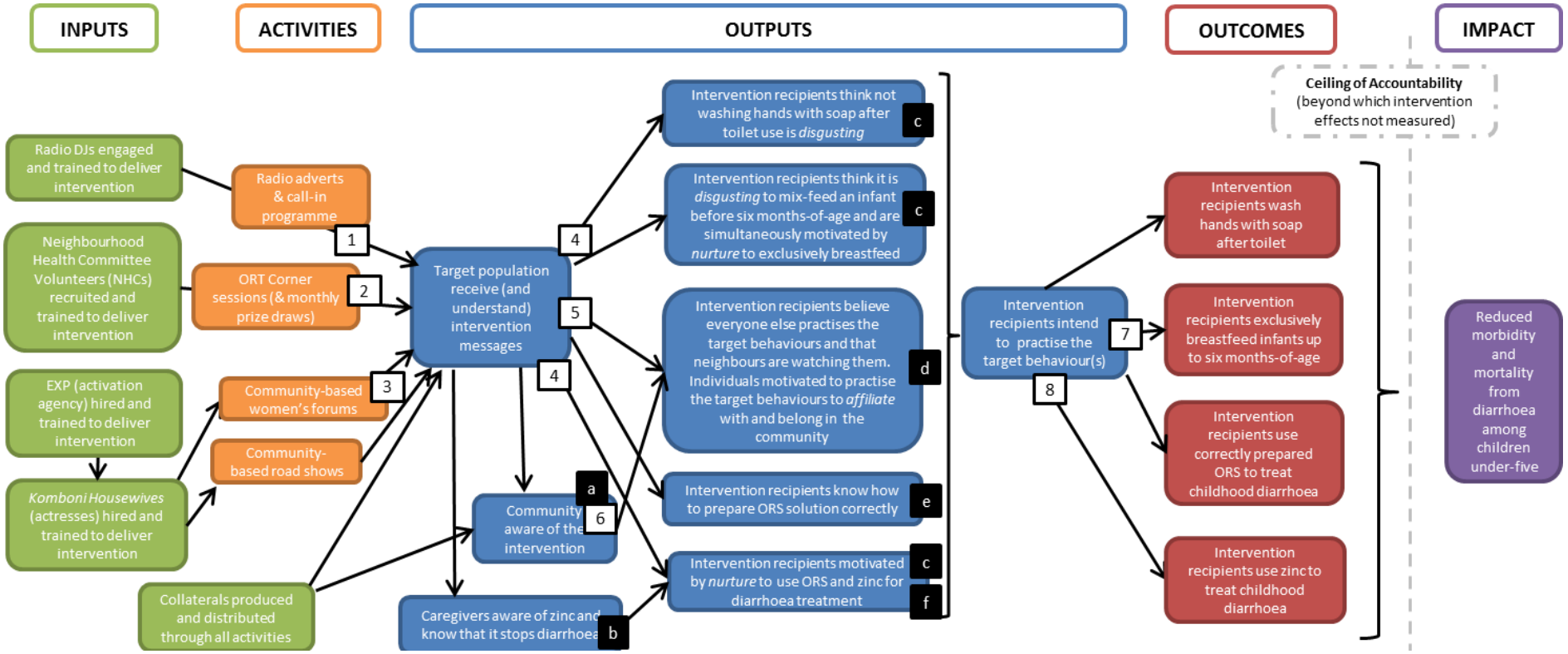
As described in Chapter 2, theory of change models can guide the design, development and evaluation of interventions. They can provide hypotheses as to the links between these activities and desired intervention outcomes. The hypothesised links in a theory of change model are built from local knowledge, practical experience and relevant social science theory (De Silva et al., 2014, National Institute for Health and Clinical Excellence, 2007). Consideration also needs to be given to any contextual factors that may affect intervention uptake, as well as the assumptions that need to hold true if change is to be brought about through the hypothesised pathway (Fulbright-Anderson et al., 1998, Vogel, 2012).

The theory of change for the *Komboni Housewives* intervention shown in Figure 5-6 evolved as the intervention took shape and the intervention components and activities were mapped onto the pathway of change. Mapping out the theory of change visually helped to ensure that the intervention content stayed true to the underlying intervention theory and the intervention's purpose, which was especially important as the intervention targeted four behaviours.

The model illustrates how - based on behaviour theory and prior experience - the processes of the intervention outlined in Section 5.2 were hypothesised to lead to the desired long-term impact of reduced diarrhoea-associated morbidity and mortality among children under-five. The model also highlights the external factors that needed to exist for changes to occur as anticipated. First, the target population needed to be exposed to the intervention and receive the intervention messages. In order for this to happen, it was necessary for the intervention to be delivered as intended, the implementers needed to be knowledgeable and motivated and the intervention needed to penetrate sufficiently the target population. Next, receipt of the intervention messages would need to lead to some specific changes: intervention recipients would need to associate the target behaviours with the relevant drivers (*disgust, nurture* or *affiliation*), they would need to be aware of zinc and they would need to have gained the ability to prepare ORS solution correctly. These changes would depend on community support, elicitation of the desired emotional responses following exposure to the intervention, and identification of the target population with the intervention

concept and the *Komboni Housewives.* In turn, it was recognised that a mother would not be able to change her infant feeding practices even if she wished to, if she had already initiated mixed-feeding, nor could she use zinc, if it was not provided at the clinic or available for purchase. Theoretical reasons were attached to links between the intermediate outcomes and a change in the target behaviours. These links are shown in Figure 5-6.

The intervention's theory of change should be testable, i.e. be associated with clearly-defined indicators to measure intervention implementation, receipt and uptake. The next chapter describes the design of the outcome and process evaluations of the *Komboni Housewives* interventions. The theory of change was tested through the process evaluation.



Assumptions (to be measured, possible mediators or moderators of intervention effect):

1. Radio stations run sessions as scheduled and cover intended content; DJs are knowledgeable and motivated; Intervention areas have good radio reception and reach; radio is listened to (at time of show) by target population.

2. Target population attend sessions; intervention delivered as intended (content and quality); Implementers motivated, knowledgeable and have sufficient time; Clinic environment and staff are supportive.

3. Target population recruited from within community & attend willingly; intervention delivered as intended (content and quality); implementers motivated and knowledgeable about intervention; intervention saturates intervention area (i.e. sufficient coverage and intensity).

4. Intervention demonstrations successfully elicit desired emotional responses: feelings of *disgust* and *nurture*

5. Intervention recipients identify with *Komboni housewives* and intervention concept & believe in credibility of NHCs / KHs

6. Social environment is supportive (injunctive norms) and holds positive attitudes to and beliefs about the target behaviours

7. The child is not already mixed-fed (i.e. it is possible to EBF).

8. Zinc is available and provided at clinics or purchased on prescription.

Rationale for pathway of change (suggested by theory and experience):

a. Unusual & new nature of intervention may create discussion in community and spread messages indirectly through a social network (Diffusion of innovation theory (Rogers, 2010); Social network theory (e.g. (Hawe and Ghali, 2008).

b. Knowledge can be important in driving behaviour when awareness of the behaviour is lacking (Aunger and Curtis, 2016).

C. Disgust and nurture are important evolved motives of human behaviour (Aunger and Curtis, 2013, Aunger and Curtis, 2015). Behaviour change can be achieved by attaching new / enhancing existing motivations for practising a behaviour (Aunger and Curtis, 2016).

d. Social norms theory (e.g. Fishbein & Ajzen 2010) describes beliefs people have about what others in their social network do (descriptive norms) which causes people to want to behave like others to gain acceptance. Social norms are an important constuct in Evo-Eco (Aunger & Curtis 2013) and most other theories of behaviour. Creating the impression that everyone does the target behaviours could create a new norm. Affiliation can determine behaviour, it is the human motive that causes people to want to belong to social groups (Aunger and Curtis, 2013) and may be triggered by associating practice of the target behaviours with achievement of social approval.

e. 'Action Knowledge' is a prerequisite for practice of behaviour (Frick et al., 2004, Michie et al., 2015).

f. Evidence from other studies suggests that co-promotion of ORS and zinc can drive uptake of ORS (Fischer Walker et al., 2009).

Figure 5-6.Theory of change model of the Komboni Housewives intervention

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PART III

Intervention evaluation

Chapter 6: Cluster-randomised trial and process evaluation methods

6.1 Overview of chapter

The impact of the *Komboni Housewives* intervention was assessed between January and November, 2014 in a cluster-randomised trial with an embedded process evaluation. This chapter presents the design, rationale and methods for both the outcome evaluation (Section 6.2) and the process evaluation (Section 6.3). The results of the outcome evaluation are reported in Chapter 7 and process evaluation findings are presented in Chapter 8.

6.2 Cluster-randomised trial: outcome evaluation methods

6.2.1 Study setting

The Cluster-randomised trial (CRT) was conducted in Lusaka Province because it was the implementation area for the Programme for the Awareness and Elimination of Diarrhoea (see Chapter 1 for more details). The trial was conducted in three of the four districts in Lusaka province: Lusaka, Kafue and Chongwe. Luangwa district was not included due to the low population density. Further detail on the characteristics of the study setting are described in the formative research methods presented in Chapter 3, Section 3.3.1.

6.2.2 Study design and rationale

The outcome evaluation aimed to assess whether the intervention was associated with improved caregiver practice of four diarrhoea control behaviours. We chose to evaluate the *Komboni Housewives* intervention using a two-arm, parallel, CRT design after discounting a number of alternative options. As the intervention was delivered at community level, a cluster design was most appropriate. In order to conclude that observed changes in behaviour were due to our intervention, a

comparison group was required. Comparison areas need to have similar characteristics to intervention sites and this is difficult to achieve without randomisation, even if matching is used (Hayes and Moulton, 2009). As the evaluation was planned before the start of the intervention and there was no political pressure to intervene in specific areas, it was feasible to randomise clusters to receive the intervention. It was also ethically justifiable, as the benefit of the intervention was unknown and ORS and zinc treatment for diarrhoea were still available at clinics in control sites even though they were not promoted (Rosen et al., 2006).

As individuals in control sites would have the potential to be exposed to the radio component of the intervention, we considered using an additional, non-randomised comparison group from another part of the country. Concerns about the lack of comparability between study sites, coupled with other logistical challenges, meant that we did not pursue this option. CRTs of community interventions with behavioural outcomes, where only large effect sizes are of public health interest can be conducted with a relatively small number of clusters (Schmidt, 2016, Hayes and Moulton, 2009). However, delivery of the intervention in both peri-urban slums and rural villages meant that unrestricted randomisation could not be relied upon to balance potential confounders between study arms (Hayes and Moulton, 2009). As the intervention targeted multiple behaviours, we decided to restrict randomisation through stratification on district (urban-rural location).

6.2.3 Randomisation of clusters

A cluster was defined as the geographical catchment area of a government clinic, since a part of the intervention was to be delivered through the clinic structure and part via community events.

Sixteen clusters were randomly selected from a sampling frame of 81 government clinics in a 2:1:1 ratio based on district, in order to include equal numbers of peri-urban and rural clusters. This resulted in the inclusion of eight clusters in peri-urban Lusaka and four each in rural Chongwe and Kafue. A statistician

unconnected with the study randomly allocated half of the clusters in each district to intervention or control (standard care at clinics only).

The *Komboni Housewives* intervention aimed to increase zinc awareness and use. However, as zinc availability in Zambia is poor (Chilengi et al., 2016), zinc needed to be supplied to intervention clinics throughout the intervention period. In order to allow sufficient time to procure zinc in intervention clusters, intervention and control clusters were randomised before baseline data were collected. Cluster allocation was concealed from the study team at this time.

The locations of the sixteen randomised sites are shown in Figure 6-1.

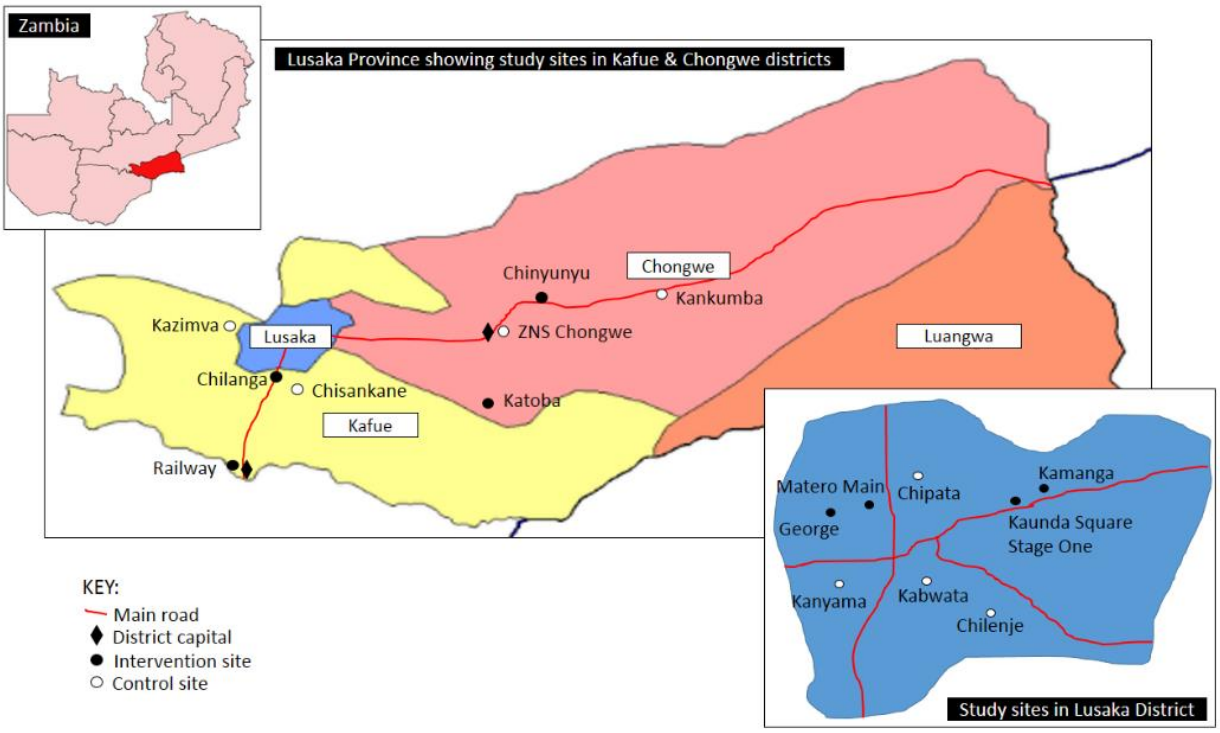

Figure 6-1. Intervention and control clusters and their locations in Lusaka Province

6.2.4 Sampling

Data were collected at baseline and again at endline, 4-6 weeks after the end of the intervention. The 'fried-egg' design (Hayes and Moulton, 2009) was applied to restrict sampling within each cluster to the 'yolk' to reduce the potential for contamination at the cluster periphery, as people do not always attend their nearest clinic.

The perimeter of the sampling area in each cluster was marked out on foot and photos were taken of key landmarks as shown in Figure 6-2. The same sampling area was used at baseline and endline to avoid potential selection bias resulting from the inclusion of different populations.

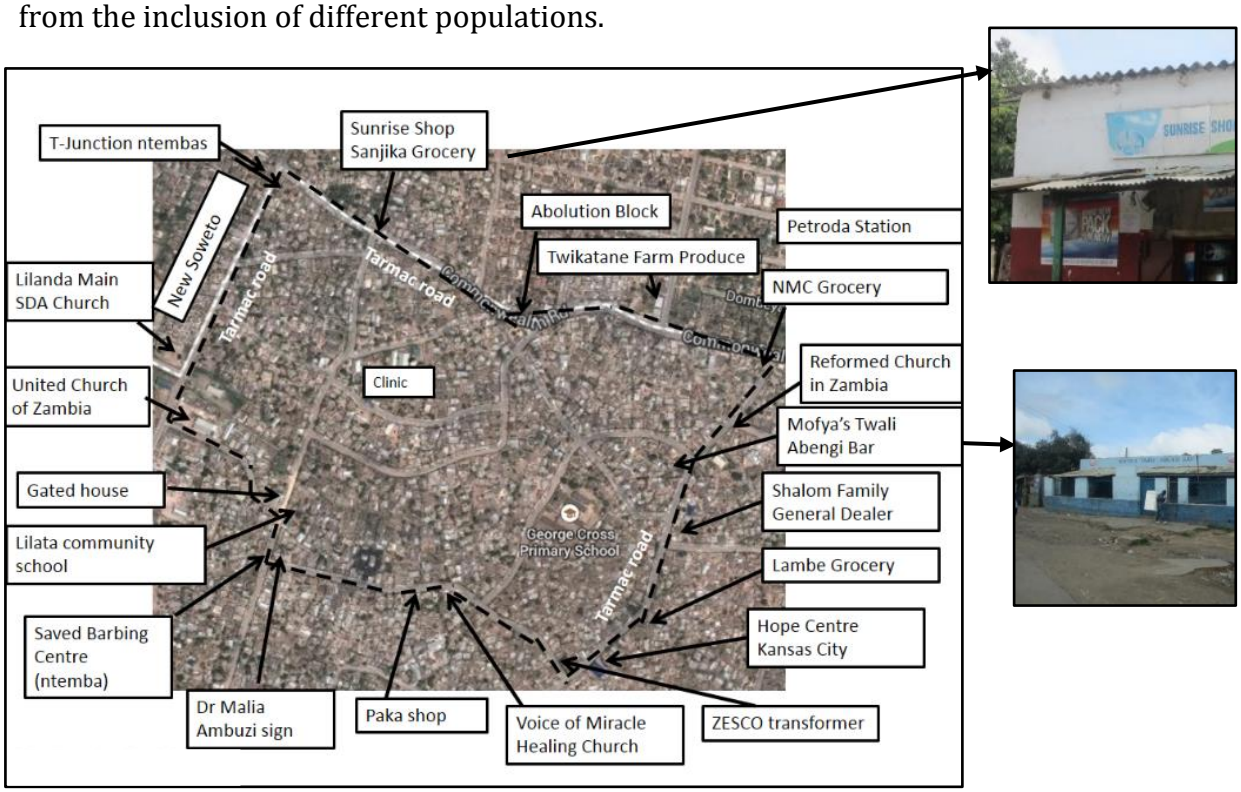

Figure 6-2. The evaluation sampling area in a peri-urban intervention area

The process of sampling within clusters is important because it affects the representativeness of a sample. Ideally, households should be selected from a sampling frame which includes a list of all of the households in the cluster. However, we could not identify an adequate sampling frame, as it was not possible to identify eligible households from clinic records, because such registers did not exist, and even if they had, such a list would almost certainly not have been complete.

We used the 'Random Walk' approach used in the Expanded Programme for Immunisation (United Nations Children's Fund, 1995) supported by GPS data. A number of potential starting points were marked on a map of the sampling area (Figure 6-3). As enumerators worked in teams of four, peri-urban clusters were divided into four segments and random starting points were selected for each

enumerator. Enumerators were oriented on their area on foot or by car prior to the start of data collection.

Figure 6-3. Map of Kamanga Compound showing possible start points for sampling within a cluster

Within each segment a specified number of individuals meeting the eligibility criteria needed to be recruited. The team followed a standardised approach: when a household was not eligible, or the household head declined to participate, the next household to the left (when exiting the home) was approached. If a caregiver was eligible but unavailable, the household was revisited later that day or the next day to try to recruit them. Each time an eligible individual was recruited a gap was left to avoid recruiting immediate neighbours (one house in rural areas and three in urban areas).

6.2.5 Study population

Two sets of eligibility criteria were applied:

1. Mothers of infants under six months-of-age were selected to assess exclusive breastfeeding. Handwashing with soap outcomes were also measured.
2. Primary caregivers of a child under-five with current or recent diarrhoea were recruited to measure ORS and zinc outcomes.

Diarrhoea was defined as *"three or more loose stools within 24 hours, or more frequent motions than normal for the individual"* (WHO, 2005). 'Current' diarrhoea needed to have begun at least 24 hours before the time of recruitment, and 'recent' was defined as diarrhoea on one or more of the preceding seven days (period prevalence). A seven day cut-off was selected, as this was long enough to enable recruitment of sufficient caregivers and short enough to reduce recall bias (Schmidt et al., 2011).

Only one child was enrolled per household. When a household fulfilled both eligibility criteria, the youngest child was enrolled, as it was more difficult to recruit mothers of infants under six-months: two-week prevalence of childhood diarrhoea in Zambia at the time of the study was 16%, whilst the prevalence of pregnancy amongst women 15-49 years of age was 11% (Central Statistical Office [Zambia] et al., 2009). An additional criterion at endline was the requirement that participants had been resident in their area (intervention or control) since the start of the intervention period.

6.2.6 Outcome measures

In complex interventions it is not uncommon to define a range of outcome measures and assess success independently for each specified outcome (Pronyk et al., 2006, Craig et al., 2008). We defined one primary outcome for each of the four target behaviours. The evaluation aimed to establish whether the intervention was feasible and could change behaviour. It would not have been appropriate to invest time and money in a large study to measure health outcomes before these fundamental principles had been tested.

Table 6-1 lists the four primary and eight secondary outcome measures adopted to measure the target behaviours, along with my definition of each of these indicators.

Table 6-1. Primary and secondary outcome measures for each target behaviour

Target	Indicator	Definition
Primary outcomes		
Exclusive breastfeeding	Proportion of infants 0-5 months exclusively breastfed	Infants were defined as being exclusively breastfed if they had received no food or drink other than breast milk or vitamins / medicines in the preceding 24 hours and had never consumed common foods (porridge) or maize-based drinks (maheu). The definition is applied *post-hoc* after studying the list of foods and drinks reported to have been consumed.
Handwashing with soap	Proportion of faeces-related events observed to be associated with handwashing with soap	Observed handwashing with water after i) use of a latrine or ii) cleaning a child's bottom or clearing up faeces as a proportion of all occasions when latrine use and child defecation are observed.
ORS	Proportion of caregivers observed to correctly prepare ORS	Observed demonstration of ORS preparation, with correct preparation defined post-hoc using a checklist, pouring the entire contents of a sachet of ORS into 1 litre of clean water (boiled or chlorinated).
Zinc	Proportion of childhood diarrhoeal episodes receiving zinc	Measured by caregiver self-report that the child had received at least one zinc tablet since the start of their diarrhoeal episode, where diarrhoea is defined as "three or more loose stools within 24 hours, or more frequent motions than normal for the individual" (WHO, 2005).
Secondary outcomes		
Exclusive breastfeeding	Proportion of infants 0-2 months exclusively breastfed	As defined for the primary outcome, except population is restricted to infants 0-2 months.
	Proportion of infants 0-5 months predominantly breastfed	Predominant source of nourishment is breast milk, but the infant may also receive liquids (e.g. water and water-based drinks, fruit juice).
Handwashing with soap	Proportion of key handwashing times observed to be associated with handwashing with soap	Observed handwashing with soap at key times, defined as: i) before eating; ii) before feeding a child; iii) before preparing food; iv) after use of a latrine and v) after cleaning up a child's stools.
	Proportion of all observed handwashing events associated with soap use	Observed use of soap when hands were washed at a key time or any other observed time.
ORS	Proportion of childhood diarrhoeal episodes receiving ORS	Measured by caregiver self-report that the child had received at least one sachet of ORS since the start of their diarrhoeal episode. See primary outcome for zinc for definition of diarrhoea.
	Proportion of caregivers of a child with diarrhoea with ORS available in the home	Observed presence of one or more ORS sachets and /or ORS solution in the home at the time of the survey.
Zinc	Proportion of caregivers aware of zinc as a diarrhoea treatment	Caregiver self-report that they have i) heard of zinc and ii) can spontaneously recall that it is used in diarrhoea treatment.
	Proportion of caregivers who have ever used zinc to treat diarrhoea	Self-reported use of zinc to treat this episode of diarrhoea and / or use of zinc to treat previous episodes of diarrhoea in this or another child.

6.2.7 Rationale for selection of outcome measures

6.2.7.1 Exclusive breastfeeding

The WHO indicator states that an exclusively breastfed infant receives nothing but breast milk (including expressed breast milk or breast milk from a wet nurse), with the exception of ORS, vitamins, minerals or medicines (WHO, 2008). The indicator is derived from caregiver self-report of the liquids and foods consumed by the infant during the previous day (WHO, 2010).

The WHO indicator for exclusive breastfeeding was adopted in the absence of a more objective measure. The 24-hour recall period allows data to be collected quickly, which is preferable for reducing recall bias. It has, however, been criticised for overestimating exclusive breastfeeding prevalence, as it can cause infants occasionally fed liquids or foods to be misclassified as exclusively breastfed (Hector, 2011). Additional follow-up questions on past consumption of common weaning foods were included to improve the sensitivity of the measure.

The precise wording of the questions used to assess exclusive breastfeeding is shown in Box 6-1. The listed foods and drinks were developed from the Zambian Demographic and Health survey (DHS) questions q578 and q579 in Section 5 of the Women's survey (Central Statistical Office [Zambia] et al., 2009) and from formative research on commonly-consumed items (see Chapter 4). This list of items was finalised during piloting.

Box 6-1. Questions to assess exclusive breastfeeding status of infants 0-5 months-of-age

Infant feeding practices

6 Think about yesterday. Which of the following has [NAME] eaten and drunk since this time yesterday?

Read out each item to the participant and record no or yes for each.

	NO	YES
Vitamins, medicine		
Plain water		
Sweetened water or Zigolo		
Fruit juice		
Tea		
Maheu or super-shake (or equivalent)		

	NO	YES
Infant formula (e.g. S26)		
Powdered (e.g. Cowbell, Nido) or fresh milk		
Other liquids (e.g. soup)		
Cereal, porridge or cerelac		
Nshima		

Other, specify: _____

7 Has [NAME] ever eaten porridge? No ☐ 1 --> GO TO QU9 IF NO
Yes ☐ 2

8 How old was [NAME] when they first had porridge? ☐☐ months Don't know (tick) ☐

Enter months or tick don't know

9 Has [NAME] <u>ever</u> consumed Maheu or super-shake? No ☐ 1 Yes ☐ 2

6.2.7.2 Handwashing with soap

No simple, reliable indicator can be universally employed to measure handwashing behaviour (Ram, 2013). Self-reported data are relatively easy to collect, but tend to overestimate handwashing rates (Manun'Ebo et al., 1997). Environmental 'spot checks' of facilities - such as the presence of soap in a kitchen or at the usual handwashing station - can also be conducted with relative ease, but they are a proxy for behaviour and more useful for predicting poor hand hygiene than making inferences about good practices (Biran et al., 2008). Structured observation captures actual behaviour and is widely regarded as the gold standard for measuring handwashing behaviour (Ram, 2013, Curtis et al., 1993).

As resources were available to hire and train sufficient numbers of competent enumerators, it was feasible to measure handwashing using structured observations.

6.2.7.3 ORS indicator

The effectiveness of ORS promotion interventions is usually measured through self-report of ORS use, typically defined as: "whether the care provider had used ORS to treat their child's current or most recent episode of diarrhoea" (Lenters et al., 2013). However, as the *Komboni Housewives* intervention was primarily concerned with improving ORS preparation, accurate measurement of the impact of the intervention required a more relevant primary outcome measure. In the formative research described in Chapter 3, ORS preparation was assessed through video observation. While observation can be time-consuming, it captures actual behaviour and is thus preferable to self-report or narrative interviewing (Atkinson et al., 2000). A checklist was created for enumerators to use during observation of ORS preparation, so that video recording was not required (Box 6-2).

Box 6-2. Checklist used by enumerators to record ORS preparation during demonstrations done by caregivers

ORS Preparation

23 Ask mother if she is willing to prepare ORS for you now. Give her a sachet. Observe and record:

If she boils water you may wish to continue with other questions until water is ready

Water boiled?	Water chlorinated?	Water measured?	Measured 1 litre?	Sachet into cooled water?	Whole sachet?
No ☐	No ☐	No ☐	No ☐	No ☐	No ☐
Yes ☐	Yes ☐	Yes (after boiling) ☐	Yes ☐	Yes ☐	Yes ☐
		Yes (before boiling) ☐		NA (not boiled) ☐	
		Yes (water not boiled) ☐			

6.2.7.4 Zinc indicator

The purpose of the zinc indicator was to assess whether zinc had been used, and not to measure whether or not the zinc course was being adhered to. For this reason, the selected indicator for zinc use was caregiver self-report that the child had received at least one zinc tablet since the start of their diarrhoeal episode. This indicator aligns with the way data is collected in household surveys such as DHS, where zinc use is recorded in a response category to the question: *"What (else) was given to treat the diarrhoea"* (USAID (MEASURE DHS/ICF International), 2011). Information on zinc treatment was included in the Zambian DHS for the first time in 2013 (Central Statistical Office [Zambia] et al., 2014).

A spot check of the presence of zinc in a household was included to verify the data collected by self-report. The questions in Box 6-3 were used to assess zinc usage.

Box 6-3. Questions used to assess zinc usage

33 Have you been given or bought [NAME] any zinc to treat this episode of diarrhoea? No ☐ 1 Yes ☐ 2 --> Exposure section if NO

38 Has [NAME] been given any of this zinc? No ☐ 1 Yes ☐ 2 --> If no, go to Exposure section

39 Are you still giving the tablets? No ☐ 1 Yes ☐ 2

40 Ask to see the Zinc. How many tablets have been taken? Seen ☐ 1 Not seen ☐ 2

40a No. Tablets taken ☐☐ **of** ☐☐ **Or tick if syrup** ☐

6.2.8 Data collection

6.2.8.1 Overview of procedures

Outcomes were measured through cross-sectional surveys and through structured observation at baseline (January - February 2014) and endline (October - November 2014). The endline survey can be found in Appendix B and the observation tool can be viewed in Appendix C. The six-month intervention ran from mid-March to mid-September, 2014.

Exclusive breastfeeding and handwashing outcomes were measured amongst mothers of infants under six months-of-age, the former through a questionnaire survey (the *Under Six Months Survey*) and the latter through structured observation. ORS and zinc outcomes were measured using the *Under-Five Diarrhoea Survey* which recruited caregivers of children under-five years-of-age with current or recent (last 7 days) diarrhoea. Approximately forty households were sampled in each cluster at baseline: 20 households with a child under-five with diarrhoea and 20 households with a child under six-months. The sample size was increased to 30 in intervention clusters at endline. More detail on the rationale for increasing the sample size is provided in Section 6.2.8.4 and sample size calculations can be found in Section 6.2.11. Figure 6-4 provides a summary of data collected to measure intervention outcomes. The procedures involved in data collection are described below.

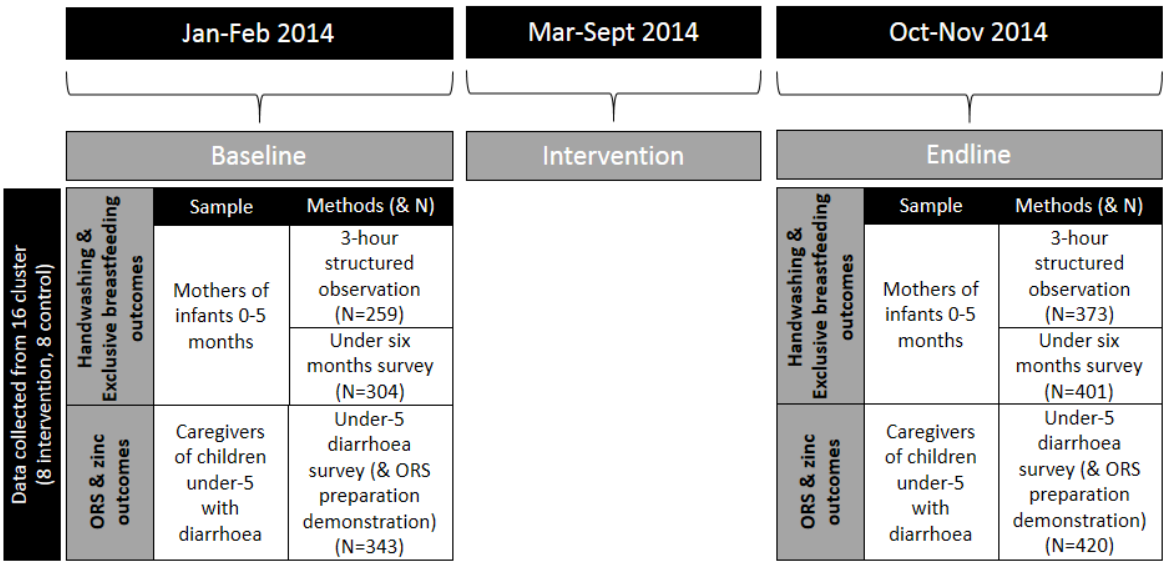

Figure 6-4 Summary of data collected to measure intervention outcomes

6.2.8.2 Cross-sectional surveys

Surveys were administered privately in the preferred language of the participant: English, Nyanja, or Bemba. All individuals were questioned on the household composition, socio-demographic characteristics, and water and sanitation facilities. In the *Under Six Months Survey,* data were collected on infant feeding and handwashing perceptions and self-reported practices. A spot check of handwashing facilities and soap availability was also conducted. In the *Under-five Diarrhoea Survey* details were recorded on the management of the current or recent diarrhoeal episode, presence of ORS and zinc within the home (by spot check) and skill in ORS preparation (by demonstration). Clear instructions were given to help the enumerator know when to read out response categories and when to record answers without prompting. It took around 45 minutes to conduct an interview, although it could take appreciably longer (up to 1.5 hours) when water needed to be boiled to prepare ORS.

Additional questions to assess intervention exposure and recall of messages were included in the household surveys conducted at endline (see Section 6.3.3.6 for details). These questions were asked at the end of the survey to avoid biasing earlier responses.

6.2.8.3 Structured observation

Structured observation involves watching an individual or group of individuals over a specified period of time and recording information on select activities in a systematic way. Observation was carried out over three hours in the early morning (from 6am to 9am) or in the middle of the day (from 11am to 2pm). The precise timing of observation was selected to maximise the opportunity of observing handwashing occasions of interest (defecation events, food preparation and eating of meals), while taking into account other data collection needs. The flexible timing enabled enumerators to conduct two observations in a day and made it easier to find a time that the participant was available. A 3-hour observation period was chosen based on logistical considerations, similar to earlier trials (Biran et al., 2014, Curtis et al., 1993) and numerous formative research studies (not always published) where the technique was honed.

Consent was taken on the day prior to observation to enable the enumerator to gain rapport with household members and familiarise themselves with the layout of the compound. To reduce potential reactivity, participants were not told the purpose of the observation and observation was conducted prior to administration of the *Under Six Months Survey*. The study also employed local, female enumerators who were unconnected with the clinics or other health programmes.

6.2.8.4 Other data collection

Additional baseline data were collected at the sixteen government health clinics involved in the trial. A facility survey captured information on the clinic environment, including the number and type of staff and facilities available at each clinic. Short, structured interviews were held with two or more clinic staff at each clinic to understand deviations from diarrhoea treatment protocols (N=32). This information was corroborated in exit interviews with caregivers of children under-five with diarrhoea leaving each clinic (N=42).

During the early stages of data collection at endline, it became apparent that intervention exposure in populous urban slums was lower than had been intended. To help include more individuals exposed to the intervention, an additional 10 households (using the same recruitment procedure) were enrolled in each intervention cluster.

Basic demographic information was collected from eligible individuals who declined to participate at both baseline and endline for the purpose of comparing the profile of participants and non-responders. Data were collected on: age of eligible child, age of primary caregiver, marital status, education level, and employment status. No identifying information was recorded.

6.2.9 Training

Enumerators had all completed higher education and were familiar with conducting research studies. They underwent a week-long training consisting of classroom and practical sessions (Figure 6-5). Daily quality control checks were conducted on all data collected.

Figure 6-5. Enumerators during the classroom training (left) and practising structured observation (right)

6.2.10 Ethics, consenting and confidentiality

The study protocol was approved by the ethics board at the London School of Hygiene & Tropical Medicine (approval number 6493) and by the University of Zambia Biomedical Research Ethics Committee (Ref 001-09-13). The Ministry of Health also gave permission for the study.

The study was explained to eligible individuals using the information sheet (available in English and Nyanja). Informed consent was obtained by signature or witnessed thumb print.

Study participants were allocated unique identifiers and data were stored in a password-protected database. Householder names and addresses were not recorded. Reported quotes and observed behaviours were anonymised.

6.2.11 Sample size

We calculated the required sample size for a two-sample comparison of proportions based on simple random sampling for each primary outcome using the *sampsi* command in *Stata 12* (StataCorp 2012, College Station, Tex.). Calculations used estimates of the prevalence of the target behaviours in each study arm post-intervention, an alpha of 0.05 and 80% power to detect the anticipated difference between the study arms. The rationale for the parameters used in these calculations is provided in Table 6-2.

Table 6-2. Justification of estimates used in sample size calculations for each primary outcome

Target behaviour	Change to detect	Rationale for estimates used to calculate sample size
Exclusive breastfeeding	% infants 0-5 months of age reported to be exclusively breastfed increases from 35% to 45%	Although DHS data states that 61% of women reportedly breastfeed exclusively up to six months, the PAED programme believed the actual figure was much lower (35%). A 10% change in behaviour was considered a realistic goal.
Handwashing with soap	% handwashing 'events' (key times) accompanied by handwashing increases from 5% to 20%	PAED set the baseline at 20% and predicted an increase to 27%, but research in many countries & experience with other HWWS programmes has shown that actual practice of HWWS at key times is generally much lower than this. The formative research did not lead us to believe this population was any different. Recent experience with a handwashing trial in India suggests a 15% increase in practice might be achievable.
ORS	% episodes of diarrhoea reported to have received ORS at home increases from 30% to 50%	PAED estimated that the baseline was 53%, but we suspected the baseline may be lower than this and opted for a more conservative estimate for the sample size calculation. We wished to be able to detect a 20% increase in behaviour.
Zinc supplementation	% episodes of diarrhoea reported to have received zinc at home increases from 0% to 15%	Zinc was almost completely unavailable and unknown, therefore the baseline was set at 0%. PAED aimed to get Zinc usage up to 40%, so 20% was a more conservative estimate, important for sample size calculations.

PAED = Programme for the Awareness and Elimination of Diarrhoea. See Chapter 1 for more details on PAED, or refer to http://www.cidrz.org/diarrhoeal-disease-control/.

We inflated the sample size estimates computed in *Stata 12* to account for clustering by multiplying the sample size by the design effect (Hayes and Moulton, 2009). Allowing for design effects based on different cluster sizes (ranging from 8 to 50 individuals) and an Intra-cluster correlation coefficient (ICC) of 0.01 based on handwashing data from a recent cluster-randomised trial by our group (Biran et al., 2014), we then computed the number of clusters required to detect estimated changes in each target behaviour. The various allowable combinations of cluster size and clusters per arm are shown in Figure 6-6.

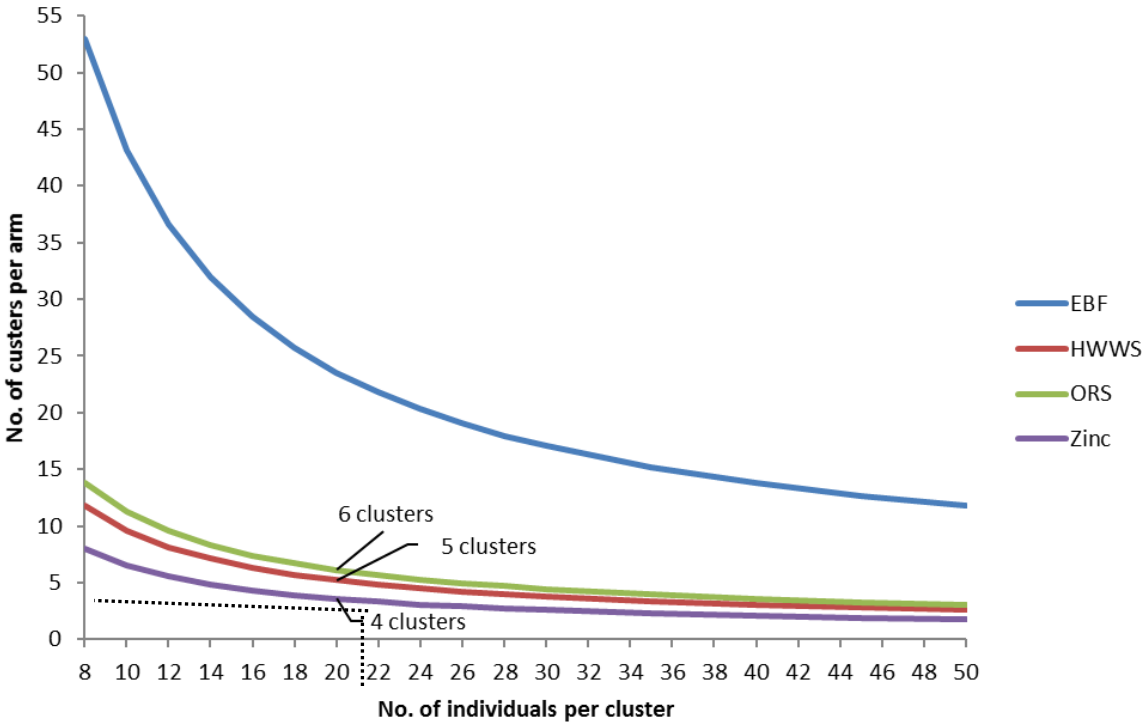

Figure 6-6. Simulation depicting sample size required to assess each primary outcome based on different combinations of cluster size and cluster number

Assuming a cluster size of 20 (with a resulting design effect of 1.19) required us to sample 120 individuals in six clusters per arm. We added two further clusters to each arm to allow for uncertainty in the ICC and possible lower effect sizes. This resulted in a total of eight clusters and a sample size of 160 individuals per arm. A 20% increase in exclusive breastfeeding behaviour was detectable with 80% power.

6.2.11.1 Recalculation of sample size using baseline data

The sample size was recalculated once the baseline data were available. The primary outcomes for the trial were also adjusted to reflect the final intervention content and behaviour change goals. Table 6-3 shows the baseline prevalence (P0), the estimated increase in prevalence following the intervention (P1) and the ICC for the revised sample size calculations for the primary outcome for each target behaviour. The higher-than-anticipated values of ICC were a concern. We therefore decided to calculate the difference in prevalence between the study arms that would be detectable with 80% power. This was done using the *clustersampsi*

command written by Hemming and Marsh. The equations and logic behind these calculations are outlined in their paper on sample size calculations in CRTs with fixed cluster size or number (Hemming et al., 2011). The results of these calculations reduced the power to detect the desired absolute changes in behaviour for all outcomes except ORS preparation (Table 6-3).

Table 6-3. Implications of baseline prevalence and ICC on detectable difference and power

Primary Outcome	INITIAL CALCULATION*		RECALCULATION (USING BASELINE DATA)			Achievable power of trial based on recalculation values of P0 and P1	Minimum detectable difference possible with 80% power
	Estimated proportion in absence of intervention (P0)	Estimated proportion in presence of intervention (P1)	Actual proportion in absence of intervention (P0)	Estimated proportion in presence of intervention (P1)	Intra-cluster correlation coefficient (ICC)		
Proportion exclusive breastfeeding of infants 0-5 months-of-age	0.35	0.45	0.33	0.53	0.07	62%	25%
Proportion of defecation events when hands are washed with soap	Not done	Not done	0.25	0.40	0.09	38%	26%
Proportion of caregivers able to correctly prepare oral rehydration salt solution	Not done	Not done	0.31	0.51	0.001	93%	16%
Proportion of childhood diarrhoeal episodes treated with zinc	0	0.15	0.06	0.21	0.09	63%	24%

**Using an estimated ICC of 0.01.*

6.2.12 Statistical analyses

Data were double-entered into *Epi Data version 3.1* and cleaned prior to analysis.

6.2.12.1 Analysis of baseline data

The baseline population was characterised to assess the extent to which randomisation succeeded in achieving balance between intervention and control arms (Hayes and Moulton, 2009). Summary measures (means or proportions) were calculated for key variables stratified by study arm. The characteristics to be described at individual and cluster level were specified *a priori* in the analysis plan

in accordance with CONSORT guidelines for the reporting of baseline data in a CRT (Campbell et al., 2012).

The following comparisons between study arms were made:

- At Individual Level
    - Socio-demographic characteristics: household size; age of caregiver / age of eligible child; education level; employment status; socio-economic status; WASH facilities
- At Cluster Level
    - Prevalence of the target behaviours.

Baseline characteristics for individuals were presented as overall summaries per arm. The ICC for each primary behavioural outcome was calculated using the *loneway* command in *Stata 14* so that sample sizes could be recalculated for the follow-up study (see Section 6.2.11.1).

Few eligible individuals declined to participate (N=13) so it was not possible to assess the potential for selection bias by comparing the profile of participants and eligible non-responders as had been intended.

6.2.12.2 Analysis of behavioural outcomes

Primary analysis was conducted on an Intention-to-treat basis to assess whether the intervention was effective as delivered. Per-protocol analyses were also performed to assess whether the intervention succeeded in changing behaviour among those directly exposed to it. Intervention exposure was defined as attendance at a women's forum and/or a clinic session and/or a road show and/or a prize draw event. Handwashing with soap messaging was not part of intervention component delivered in the clinics, so the exposure variable for handwashing outcomes was modified accordingly. Exposure to the radio show in both arms was measured but not adjusted for.

Due to the small number of clusters, cluster-level analysis was performed to account for potential correlation of data within clusters. This form of analysis accounts for clustering by aggregating data within each cluster and comparing cluster-level summary measures. The outcome of cluster-level analysis is similar to

that obtained using individual-level regression approaches (Chuang et al., 2002), which are not appropriate for use in studies with a small number of clusters (Hayes and Moulton, 2009). Cluster-level summaries for each behavioural outcome were computed as the mean of cluster-level means. An unpaired t-test was used to compare crude proportions between study arms and to compute confidence intervals. Permutation tests were also carried out as a sensitivity analysis and the ICC for each primary outcome was calculated (Hayes and Moulton, 2009).

The two-step approach recommended by Hayes & Moulton was followed to adjust for cluster-level baseline values of each outcome measure (and age of the child at endline to measure breastfeeding outcomes) (Hayes and Moulton, 2009). This involved logistic regression of binary behavioural outcomes and baseline levels of behaviour using individual household data, ignoring clustering and treatment arm allocation. Cluster-level residuals were subsequently compared. Breastfeeding rates were also adjusted for infant age. Adjusted effect measures and 95% confidence intervals (CIs) were estimated as described above, replacing cluster-level proportions with the baseline-adjusted residuals and adjusting the P-value and 95% CIs by reducing the degrees of freedom by one. These analyses were pre-specified in the analysis plan. Sensitivity analysis of breastfeeding outcomes was also carried out using a restricted dataset including only mothers with an infant under 3 months-of-age.

As variability in exposure to the intervention was anticipated, subgroup analysis based on exposure level was planned. Intervention clusters were grouped into high exposure (more than 30% of a cluster) and low exposure (30% of a cluster or less) *post-hoc* and intervention outcomes were compared with the control arm.

6.2.12.3 Other variables

Socio-economic status (SES) was measured using data on household assets and household structure through principal component analysis (PCA) following the approach described by Vyas and Kumaranayake (Vyas and Kumaranayake, 2006). All analyses were conducted in *Stata 14.* Separate SES indices for urban and rural clusters were computed, but they did not explain any more variation than a single PCA.

The final single PCA included binary variables for 13 household assets (*ownership of home, television, land for farming, non-domestic animals, mobile phone, car, bicycle, electricity, fridge, freezer, radio, water tap inside the home, flush latrine)* and the material of the floor (*cement vs. mud*) and walls (*cement / brick vs. mud*). Twenty-nine percent of the variation in wealth between households was explained by the first principal component.

6.3 Process evaluation methods

6.3.1 Evaluation aims, objectives and framework

The mixed-methods process evaluation was nested within the cluster-randomised trial. The process evaluation aimed to explore how contextual and other factors associated with intervention implementation and receipt influenced uptake of the target behaviours. A further aim was to test the underlying programme theory through exploration of the change mechanisms.

The specific objectives of the evaluation were to:

1. Document how the intervention was implemented
2. Describe how the intervention was received from the perspective of both the implementers and recipients
3. Explore how context affects intervention delivery and receipt
4. Explore the mechanisms of change of the intervention

The evaluation was structured around the intervention's theory of change model presented in Chapter 5 following the approach developed at LSHTM by de Silva and colleagues (De Silva et al., 2014) and considering the Evo-Eco theory of behaviour (Aunger and Curtis, 2014). Using the theory of change as the basis for the process evaluation provided a clear structure for the evaluation of intervention implementation, receipt and context. It also aided the identification of behaviour determinants (mediators) along the hypothesised pathways to change that needed to be measured to assess causal mechanisms.

The process evaluation framework is illustrated in Figure 6-7. Eight process evaluation components were mapped onto this evaluation framework. These evaluation 'domains' were primarily influenced by Linnan and Steckler's

evaluation framework (Linnan and Steckler, 2002), but also drew on other recent guidance (Bonell et al., 2006, Grant et al., 2013). Visual representation of the evaluation domains in Figure 6-7 according to categories of 'implementation', 'receipt and mechanism of impact' and 'context' was inspired by recent guidance on process evaluation of complex interventions (Moore et al., 2015a). The evaluation domains that we included are shown in Table 6-4.

Table 6-4. Process evaluation objectives, with associated domains and research questions

Objective	Evaluation Domain	Research Question(s)
1. Document how the intervention was implemented	Fidelity & Dose delivered	What is delivered during the intervention? How and why does this depart from what was intended with respect to both quality and quantity?
	Reach	To what degree does the intervention contact the target population in each setting? Which subgroups are reached? What explains the pattern of reach achieved?
	Recruitment	How do recruitment strategies affect the pattern of reach achieved?
2. Describe how the intervention was received from the perspective of both the implementers and recipients	Participant Engagement & Responses	To what extent do intervention recipients actively engage with the intervention and understand and retain key messages?
	Acceptability	How acceptable was the intervention to recipients and implementers?
3. Explore how context affects intervention delivery and receipt	Context	How do contextual factors (events and influences in the intervention setting and environment) encourage or impede intervention implementation and uptake?
4. Explore the intervention mechanisms of change	Mediators	How do behavioural determinants change as a result of exposure to the intervention?

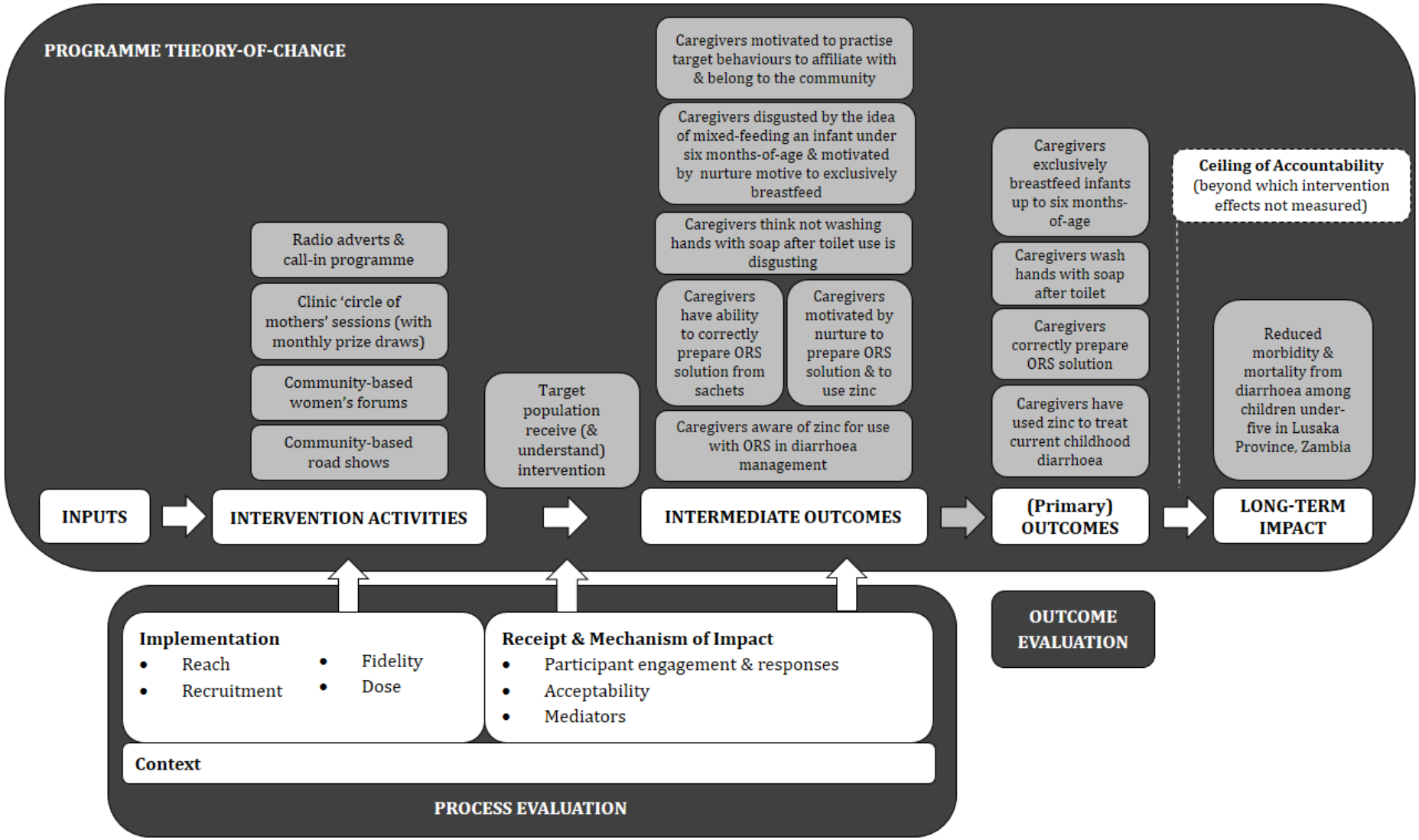

Figure 6-7. Process evaluation framework

6.3.2 Measurement of evaluation domains

This section describes the rationale for the inclusion of each of the evaluation domains in our process evaluation and the choice of measurement methods.

6.3.2.1 Fidelity and Dose delivered

Assessing fidelity is a crucial component of a process evaluation because an intervention with low fidelity would be unlikely to achieve high levels of behaviour change (Carroll et al., 2007, Wilson et al., 2010, Dusenbury et al., 2003). If an intervention lacks fidelity this also raises questions about the feasibility of replicating the intervention in another setting. Dose delivered, or completeness, is the proportion of the intended intervention actually delivered to programme participants (Linnan and Steckler, 2002). It forms part of the fidelity assessment.

Measurement of fidelity should comprise an assessment of adherence to the protocol and competence of delivery, although the latter is less commonly measured (Carroll et al., 2007, Breitenstein et al., 2010). Fidelity is considered difficult to measure well because determining how well an intervention was carried out involves some level of subjectivity. There is also no general consensus on how fidelity should be measured and no guidance on what constitutes fidelity that is 'high enough' (Hasson et al., 2012, Dusenbury et al., 2003).

6.3.2.2 Reach

Reach is the degree to which the intended audience participates in an intervention (Linnan and Steckler, 2002). Data on reach can also be used to assess whether the intervention is inclusive (Grant et al., 2013). This is important, because an intervention that fails to reach the poorest individuals cannot expect to fully impact the diarrhoea burden and it may even widen inequalities (Victora et al., 2012).

Reach is often assessed from routine process data collected on intervention attendance or coverage (Linnan and Steckler, 2002). The latter is typically measured by participant self-report of intervention attendance based on recall or recognition of defined aspects of the intervention (Valente, 2002). In public health, questions concerning intervention recall and recognition are used interchangeably. However, questions involving recall may underestimate exposure, while questions

involving recognition could overestimate exposure (although evidence of this is inconclusive (Morris et al., 2009)). Biased assessment of intervention exposure can thus cause incorrect conclusions to be drawn about an intervention's effectiveness (Morris et al., 2009). Accuracy can be improved by narrowing the specificity of the questions or by including 'ringers' – incorrect statements about the intervention that confirm exposure, although again the evidence is inconclusive on whether this adds predictive power (Niederdeppe, 2005).

Implementer activity logs were used to capture attendance at the main intervention components (ORT corner sessions, *Komboni Housewife* forums, road shows). However, reach was primarily assessed during the endline household surveys used to assess intervention effectiveness. I chose to measure intervention exposure using recognition questions and visual aids (materials from the intervention) to reduce the likelihood of misclassifying exposure.

6.3.2.3 Recruitment strategies

Recruitment refers to the procedures used to approach and attract intervention recipients (Linnan and Steckler, 2002). If recruitment processes affect the participation of certain subgroups of the population then intervention reach is again limited to certain subgroups (Grant et al., 2013). This can make it difficult to generalise findings. Given that clusters were quite different (particularly between peri-urban and rural areas) I decided to assess recruitment qualitatively in semi-structured interviews with the implementers.

6.3.2.4 Participant engagement and response

Participant interaction with the intervention (engagement and responses), relates to receipt and understanding of key messages, and engagement with the intervention content (Linnan and Steckler, 2002, Moore et al., 2015a). If the target audience does not understand or engage with an intervention then it is unlikely that intervention exposure will lead to a change in behaviour along the hypothesised pathway to change (Lippke et al., 2016). However, it is possible that engagement with an intervention may take the form of a subliminal cue (Aunger and Curtis, 2016).

It is far easier to assess physical presence at an intervention than it is to document 'engagement'. Some investigators have developed proxy measures for engagement, such as the time spent 'actively engaged' in an intervention (Richert et al., 2011). However, such measures are inappropriate for use during large community events. I therefore decided to assess engagement during the field observations based on visual appraisal (crowd physically sitting and paying attention) and observed levels of participation in discussions and activities.

6.3.2.5 Acceptability

Acceptability measures are not always included in process evaluations. Bonell and colleagues have suggested that assessing recipient and implementer acceptability of the intervention can improve the external validity of a study's findings (Bonell et al., 2006). However, in this evaluation, acceptability was primarily studied for another reason: participant acceptability influences whether the intervention is likely to be taken up (for example, (Greenland et al., 2011)) and can determine how the intervention is relayed and responded to by others in the social environment (Kraft et al., 2000).

6.3.2.6 Context

Context describes events and influences in the intervention setting and environment that could encourage or impede the intervention. Hawe and colleagues have described exploration of how intervention context impacts intervention effects as *"a new methodological frontier"* (Hawe et al., 2004). Full investigation of context in the ways described elsewhere (Israel et al., 1995) was beyond the scope of this evaluation. Nevertheless, a deliberate attempt was made to capture some specific aspects of the context, namely: i) how the nature of the population cluster affected intervention delivery and receipt; ii) how the clinic environment and work load of the NHCs affected implementation of the clinic sessions; and iii) how zinc availability and prescription in clinics affected outcomes during the intervention period.

6.3.2.7 Mediators

Assessment of mediators involves measuring intermediate processes that explain subsequent changes in outcomes (Moore et al., 2015b). Measuring specific constructs, or behavioural determinants, on the hypothesised causal pathway outlined in an intervention's theory of change allows exploration of an intervention's mechanism of change. Mediators can be measured qualitatively or quantitatively (Bonell et al., 2012). As I intended to perform mediation analysis (MacKinnon et al., 2007), I primarily collected quantitative data on the intermediate outcomes specified in the intervention theory of change. Mediators were also explored qualitatively in focus group discussions.

6.3.3 Data collection

6.3.3.1 Overview of procedures

Figure 6-8, below, provides an overview of the data collected during the process evaluation.

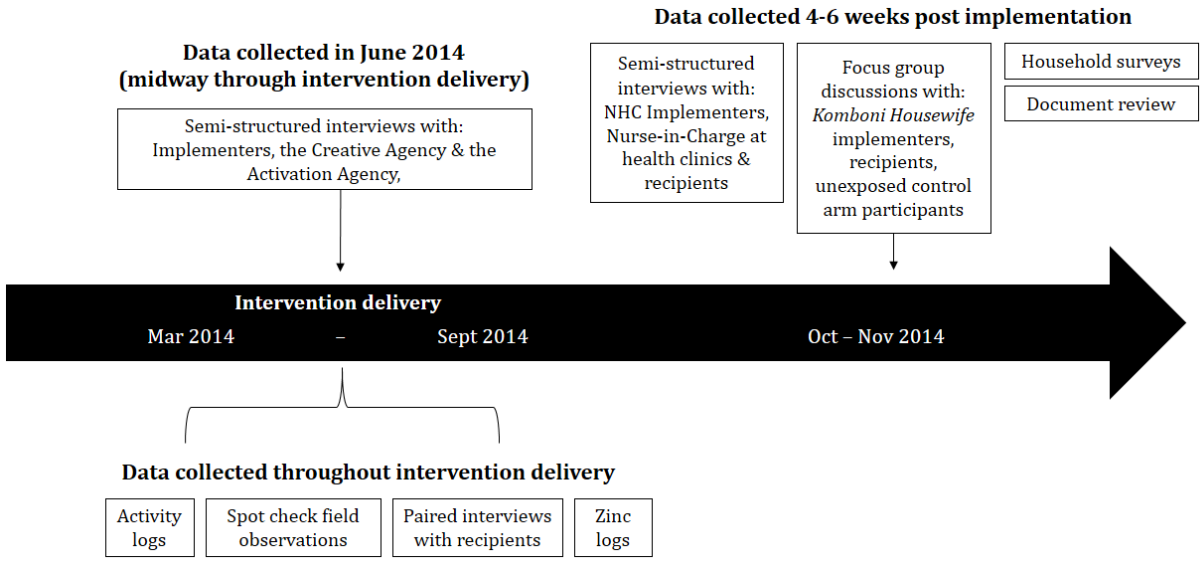

Figure 6-8. Timeline of collection of process data

Process data were collected from the eight intervention areas throughout the six-month intervention period to assess intervention implementation - primarily fidelity and dose delivered. Activity logs were completed by the implementers for each ORT corner session, forum and road show. These reports, which also

documented intervention attendance, were supplemented by spot check field observations to independently assess adherence to the protocol and competence of delivery. The radio component of the campaign was monitored by CIDRZ staff. Intervention recipients were interviewed in pairs following these field observations to assess message acceptability and comprehension.

Semi-structured interviews were carried out midway through intervention implementation with a selection of implementers, with the Creative Agency *(DDB)* and with the Activation Agency *(EXP)* in charge of the implementation of the forums and road shows. These interviews served to support quantitative data on fidelity and to evaluate how recruitment procedures influenced intervention delivery.

Further process data were collected in all 16 intervention and control clusters during October and November 2014, four to six weeks post-intervention. Quantitative data on intervention reach and behavioural mediators were collected via the household surveys used to assess intervention outcomes. These data were complemented by the findings of semi-structured interviews and focus group discussions with implementers, intervention recipients, and intervention non-recipients.

Tool development was guided by examples in the literature (Linnan and Steckler, 2002, Baranowski and Stables, 2000, Chandler et al., 2013, Hargreaves et al., 2010, Saunders et al., 2005) and the research needs. All tools were piloted during the intervention dry run. Enumerators involved in collecting data through the household survey were trained as described above. Implementers were trained to complete their activity logs during intervention piloting. They were instructed to complete their logs at the end of an event and these logs were compared with the records of the trainer. A trained CIDRZ staff member conducted the spot check field observations. A selection of the tools used in the process evaluation can be found in Appendix D. Table 6-5 provides a summary of the data collected for the process evaluation.

Table 6-5. Overview of process evaluation methods

Research Method or Data Source	Data Type	Respondents	Core Information Sought	Purpose of Information	Timing
Activity logs	Quantitative	NHC & *Komboni Housewife* implementers	Number of individuals from target population attending Forums and ORT Corner Sessions. Number of men, women and children attending Road Shows. Activities conducted, availability of supplies and challenges faced	Fidelity, dose delivered, reach	Throughout intervention
		CIDRZ staff	Content and quality of delivery of Radio shows	Fidelity	Throughout intervention
Spot check field observations	Quantitative	CIDRZ staff	Content and quality of delivery and participant engagement, according to an observation checklist. Contextual information on delivery & receipt in clusters, including features of each site.	Fidelity, participant engagement, context	Throughout intervention
Semi-structured interviews	Qualitative	NHC & *Komboni Housewife* implementers	Successes and challenges of intervention delivery from perspective of the implementers Recruitment strategies and challenges in each cluster (to enable comparison with the levels of reach achieved in that cluster) Acceptability of intervention messages and activities	Fidelity, recruitment, context, acceptability, participant engagement & responses	Midway through intervention & 4-6 weeks post intervention
		Creative Agency (DDB) and Activation Agency (EXP)	Reasons for any deviations from planned activities	Fidelity	Midway through intervention
		Nurse-in-Charge at intervention clinics	Information on the (clinic) environment and work load of staff Health Centre perspective on ORT Corner Sessions	Context, acceptability	4-6 weeks post intervention
		Intervention recipients (pairs)	Comprehension of messages and emotional responses to the intervention. Acceptability of intervention messages and activities	Participant responses, acceptability	Throughout intervention
		Intervention recipients	Retention of key messages and reflections on the intervention	Participant responses	4-6 weeks post intervention
Focus group discussions	Qualitative	*Komboni Housewife* implementers	Successes and challenges of intervention delivery from perspective of the implementers Recruitment strategies and challenges in each cluster (to enable comparison with the levels of reach achieved in that cluster) Data on delivery & receipt in clusters, including features of each site Acceptability of intervention messages and activities	Fidelity, recruitment, context, acceptability, participant engagement & responses	4-6 weeks post intervention
		Intervention recipients	Retention of key messages and reflections on the intervention. Reactions to gossip in relation to the target behaviours	Participant responses, mediators	4-6 weeks post intervention
		Unexposed control arm participants	Reactions to gossip in relation to the target behaviours	Mediators	4-6 weeks post intervention
Household survey	Quantitative	Sample of individuals in intervention arm and control arm	Proportion of sample reporting attendance of each intervention component / listening to the radio show at least once in each intervention and control cluster. Recall and recognition of intervention concept, messages. Quantitative capture of indicators relating to hypothesised behavioural determinants	Reach, participant responses, mediators	At baseline (mediators) & 4-6 weeks post intervention
Zinc supply logs	Quantitative	Clinics & Pharmacies in intervention & control sites	Data on zinc supply	Context	Throughout intervention
Facility surveys	Quantitative	Clinic staff	Features of each clinic environment	Context	At baseline
Document review	Quantitative	Intervention Schedule Spreadsheet	Information on deviations from planned activities	Fidelity	4-6 weeks post intervention

Note: NHCs (Neighbourhood Health Committee volunteers) implemented the intervention at the clinics (ORT Corner Sessions), the hired actors (the Komboni Housewives) implemented the forums and road shows and were managed by EXP (an Activation Agency)

6.3.3.2 Activity logs

Activity logs were used to assess fidelity and dose delivered, and to provide information on intervention attendance to allow reach to be computed. Each week the Activation Agency (*EXP)* compiled an electronic report of the forums carried out that week by the *Komboni Housewives*. The report captured the date and location of the forum, the intervention materials given out (certificates and stickers) and the number of participants. As the forums took place in homes in the community they also attracted other, non-target women who could not be turned away without causing offence. Head counts distinguished between attendees from the target population and other women. Head counts were carried out shortly after the start of each forum. The forum reports also indicated whether the forum had connected with the radio show and captured (from the perspective of the implementer) what had worked and had not worked well that week. The reported problems included issues with the location of the forum, recruitment, radio call-in, lack of supplies, or unexpected incidents that affected the running of the forum. Photos were attached to all reports for verification purposes. Similar electronic reports were compiled for each of the eight road shows.

Paper-based activity logs were also completed by the Neighbourhood Health Committee volunteers (NHCs) who facilitated the ORT Corner Sessions at the clinics. These logs similarly captured information on attendance levels and materials given to participants, as well as any issues identified by the NHCs that affected the delivery of the sessions.

The activity log for the radio show was the only log not completed by the implementers. CIDRZ staff tuned in to listen to every radio show in the first two months of implementation, after which the frequency of monitoring decreased. The log captured whether or not the radio show connected with the forum, the topics that were discussed and any issues with delivered messages. Any deviations from the intervention manual were immediately addressed with the radio show hosts.

6.3.3.3 Field observation

Unannounced field observations were carried out to spot check whether the forums and ORT corner sessions were taking place as intended and to document what was delivered, the quality of delivery and participant engagement. Field observations took place throughout intervention delivery, but were scheduled more frequently during first few months of implementation. Delivery of the ORT corner sessions was more frequently observed than delivery of the forums, because the sessions were implemented by different teams of NHCs at each clinic.

A structured reporting form was used to capture information on the context, fidelity of implementation and participants' reactions to the intervention. This form included sections to describe the physical setting and set-up of the event as well as each activity within the session. Observations on the competence of the implementers and comments on participant engagement were also captured on this form. The same evaluator conducted all field observations to reduce inter-evaluator differences in reporting of these subjective measures. If delivery was suboptimal, the implementers were given immediate feedback at the end of the event.

6.3.3.4 Semi-structured interviews

Semi-structured interviews were conducted with intervention recipients, the Creative Agency (*DDB Iris*), the Activation Agency (*EXP*) and with the *Komboni Housewife* and NHC implementers.

<u>Intervention recipients</u>

Intervention recipients were interviewed at two different stages during the process evaluation: immediately following attendance at an intervention event and following the endline household survey. Initial interviews were conducted with intervention recipients. These individuals were selected based on their proximity to the evaluator, who carried out these interviews following completion of each spot check field observation (Figure 6-9). Participants were interviewed using a form with structured and open-ended questions to capture information on comprehension of the main messages and opinions on specific activities and the implementers. Interviews were conducted in friendship pairs to encourage

respondents to speak freely about their experiences. Pair interviewing is relatively uncommon, but has the advantage of minimising the power imbalance between the interviewer and the interviewee (Lohm, 2014).

Figure 6-9. Conducting paired interviews with intervention recipients

Intervention recipients were also interviewed at endline. These individuals were selected from household survey participants who reported having attended an ORT corner session, forum or road show. Participants were invited for interview in the order in which they were identified during data collection for the household survey. This meant that the first individuals reporting having attended a forum, ORT corner session, or road show were included. These semi-structured interviews followed a topic guide to probe on recall of the intervention content and concepts. The interviews sought to learn which intervention activities were the most memorable, and to understand, from the recipients' perspectives, any lasting impacts of the intervention on beliefs or actions. These interviews also sought to explore whether the central concept of the intervention had been effectively communicated, i.e. whether participants felt that practice of the target behaviours led to social approval, and that individuals who do not practice the target behaviours are the subject of gossip.

<u>Implementers</u>

Semi-structured interviews were carried out with NHC and *Komboni Housewife* implementers midway through intervention implementation to understand any

challenges associated with intervention delivery or recruitment. The main purpose of these interviews was to identify and act upon any contextual factors affecting fidelity or reach.

The NHC implementers at each clinic (eight pairs) were also interviewed at endline, 4-6 weeks following the termination of the intervention. These semi-structured interviews explored topics covering a number of evaluation domains, namely: fidelity, recruitment, context, acceptability and participant engagement. The questions on fidelity sought to add meaning to the quantitative data collected throughout the intervention via activity logs and spot check field observations. Implementers were asked directly about fidelity, but they were also asked questions about other factors that may have affected implementation. For example, their comprehension of the intervention following the initial training and the other demands placed on their time. Acceptability was explored through a series of questions about the activities they enjoyed delivering or found repetitive or boring, as well as their opinion on their working conditions and job satisfaction. Implementers were also asked how attentive the target population was during the sessions, and whether they thought that the intervention was acceptable from the recipients' perspective.

Creative Agency (DDB Iris) and Activation Agency (EXP)

Midway through intervention implementation, semi-structured interviews were conducted with the key contact persons at the Creative Agency who developed the intervention and the Activation Agency hired by the Creative Agency to coordinate delivery of the community-based intervention components. Topic guides were used to direct questioning on areas of fidelity of implementation, recruitment and the acceptability of the intervention to the implementers. In particular, the interviews sought to gain a deeper understanding of intervention management and decisions made concerning any changes to recruitment and delivery strategies.

Nurse-in-Charge at intervention clinics

The final series of semi-structured interviews involved the Nurse-in-Charge at each intervention clinic. These interviews, conducted after the intervention had ceased, sought to understand whether the ORT corner sessions had interfered with other activities at the clinic and whether the sessions were valued.

6.3.3.5 Focus group discussions

A focus group discussion was held with the *Komboni Housewife* implementers following the end of the intervention. The discussion explored the same topics as the above-described interviews with the NHC implementers, but took place in a group rather than individual interviews. This decision was made because the implementers worked together as one team, so collective rather than individual opinions on intervention delivery were of interest.

Focus group discussions were also held with intervention recipients and with unexposed individuals in the control arm. Each focus group included six to eight caregivers of a child under-five years-of-age. These individuals were identified through the household surveys and were included in the order in which they were identified. Six focus groups were conducted in intervention areas and three in control areas. All focus groups explored social norms and opinions on the importance of gossip and social approval and their role in determining perceptions and practice of the target behaviours. The focus groups held with intervention recipients also explored perceptions of the *Komboni Housewives*. Focus groups were selected over interviews, as the main purpose of the discussions was to explore social norms (Lewis and McNaughton Nicholls, 2014).

6.3.3.6 Household survey

Household surveys were conducted in all intervention and control clusters following the end of the intervention to assess behavioural outcomes (see Section 6.2.8.2 for more detail on data collection via household surveys). These surveys were also used to explore reach, retention of intervention messages and mediators for the process evaluation.

To avoid biasing earlier responses, questions on intervention exposure were asked at the end of the survey. Survey participants were shown the campaign logo and sticker and were asked whether they had heard of the intervention, and if so, what it had been about. Participants were then asked whether they had heard about the intervention on the radio, or whether they had attended any face-to-face intervention events. Verification questions were included to try to reduce

reporting bias, such as the location of the event, or whether a certificate had been received.

The intervention's theory of change (Chapter 5, Section 5.3) outlined specific ways the intervention activities were hypothesised to act on intermediate outcomes and lead to increased practice of the target behaviours. Data were collected on these intermediate outcomes, as well as attitudes and beliefs held in relation to each of the target behaviours that could inhibit or facilitate practice of the target behaviours. The list of potential behavioural determinants investigated was adapted from formative research findings. Box 6-4 shows the questions used to investigate potential factors mediating the relationship between the intervention and correct ORS preparation and use.

Box 6-4. Questions used to investigate attitudes and beliefs about ORS in the endline survey

ORS Attitudes and Beliefs

25 To what extent do you agree with the following statements? This is your opinon and is not right or wrong.
Read out statements and answers, tick relevant box.

		Agree	Disagree	Don't know
a	I think my neighbours always give ORS when their children have diarrhoea			
b	It makes me upset if my neighbours don't know how to make ORS correctly			
c	Knowing how to prepare ORS correctly helps me to belong in my community			
d	I cannot make a litre of ORS because my child will not finish it in one day			
e	My child can get better from diarrhoea without taking any ORS			
f	ORS in the drug store is too expensive for me to buy			
g	I think my neighbours would gossip about me if I didn't give ORS each time my child gets diarrhoea			
h	I try to give ORS every time my child has diarrhoea			
i	I think my neighbours would gossip about me if I did not know how to prepare ORS correctly			

6.3.3.7 Data on zinc supply

The availability of zinc in clinics and pharmacies over the course of the intervention needed to be monitored. Low zinc availability could limit uptake of the intervention, whilst a sudden increase in supply in the control arm could reduce the ability to detect any effects of the intervention. Health centres and private vendors near the health centres in all sites (intervention and control) were

provided with a stock card to keep a record of their zinc supply. Stock cards for drugs for other common childhood illnesses were also provided to all clinics and pharmacies near the clinics to disguise the purpose of data collection and thereby reduce falsification of records. It was intended that sites would be visited regularly over the course of the intervention to check cards had been completed and to verify that the records matched the stock. Unfortunately, however, these visits were not conducted and the data obtained from stock cards proved unreliable.

6.3.3.8 Facility surveys

Facility surveys were carried out at baseline in all 16 health clinics (see section 6.2.8.4). This information helped understand the different settings where the ORT corner sessions were taking place.

6.3.3.9 Document review

The intervention Route Map detailing all planned intervention activities was updated throughout intervention delivery. This spreadsheet was used to compare how actual activities differed from what was planned.

6.3.4 Data handling and analysis

6.3.4.1 Quantitative data

Paper records of field observation forms and activity logs were entered into MS Excel for analysis. Data on intervention exposure and behavioural determinants obtained through the household surveys were cleaned and analysed in *Stata* 14.

A single database was created from all the activity logs. The number of events held and participants in attendance at these events were computed over time and by cluster and intervention component. Many researchers have developed scores of fidelity based on checklists of core intervention components (McGrew and Griss, 2005). Composite fidelity scores were initially computed to describe fidelity according to pre-defined categories of 'adherence', 'competence', 'issues with supplies' and 'use of intervention materials'. However, these scores did not reflect

the opinions of the implementers and other fidelity data captured qualitatively. Ultimately, a matrix was created to organise fidelity data by target behaviour, intervention component and cluster.

Reach was computed as the proportion of endline survey respondents reporting attendance at one or more face-to-face event. As road shows targeted the whole community, reach was also calculated from the estimated number of attendees at each road show, using the total population in a cluster as a denominator. A census was conducted by the project team for this purpose. Due to limited time and resources for the census, in peri-urban areas the target population was extrapolated from a census conducted in part of the intervention area. A full census was conducted in rural Chinyunyu as no data were available on the target population. In Katoba, data were available on the number of households in each village, so a partial census was conducted and the target population thus extrapolated.

Reach was described according to wealth tertile (poorest, middle and least poor). These categories were computed through principal component analysis of 13 household assets (ownership of home, television, mobile telephone, land for farming, non-domestic animals, car, fridge, freezer, bicycle, radio, water tap inside the home, electricity, flush latrine) and the material of the structure (Vyas and Kumaranayake, 2006).

The proportion of survey respondents agreeing with Likert-type response questions to investigate potential mediators was analysed at cluster level following the two-step approach recommended by Hayes & Moulton (Hayes and Moulton, 2009). This approach was described in detail in section 6.2.12.2

6.3.4.2 Qualitative data

Voice recordings from all interviews and focus groups were transcribed verbatim and translated into English (where necessary). Transcripts were checked against the original audio recordings for accuracy. Transcripts were analysed thematically according to pre-specified, 'deductive' categories (Hayes, 1997) following the six-phase method put forward by Braun and Clarke (Braun and Clarke, 2006). This 'substantive' approach was deliberately selected to explore the meaning of the text

in the transcripts rather than to study its structure or the use of language (Spencer et al., 2014).

Complete transcripts were first read several times and initial impressions about the data were noted. Transcripts were then coded according to theme, taking into account some of the surrounding text to avoid losing context (Bryman, 2001). The selected themes were 'explicit': I sought to describe and interpret the content of the transcripts rather than to explore underlying meaning in the data. The pre-specified themes related to the evaluation domains: fidelity, recruitment, context, acceptability, participant responses and mediators based on the intervention concept: gossip and social approval. Identified sub-themes were specified for the four target behaviours and the face-to-face intervention components. Following indexing, a series of matrices was created in MS Excel to review data by theme and sub-theme. Patterns that were identified were summarised according to theme and sub-theme and reviewed alongside the quantitative data to explore relationships between the domains: for example, to explore the influence of recruitment strategies on the reach and dose delivered of each intervention component. A model of the proposed causal mechanism was then developed to suggest how intervention effects for each target behaviour were influenced by the fidelity of implementation, participant responses, acceptability of the intervention to the target population and implementers, and other contextual factors.

The following chapter presents the findings from the outcome evaluation (Research Paper 2) (Greenland et al., 2016). The findings from the process evaluation follow in Chapter 8.

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Chapter 7: Results from the cluster-randomised trial

7.1 Overview of chapter

This chapter presents the findings from the outcome evaluation as a published paper (Research Paper 2). Findings from the process evaluation are presented in the subsequent chapter.

7.2 Preamble for Research Paper 2

The *Komboni Housewives* intervention was created to change multiple diarrhoea control behaviours simultaneously. The intervention was informed by formative research and the links between the intervention and its intended outcomes were clearly delineated in the intervention's theory of change. Rigorous evaluation was necessary to assess whether this systematic approach to intervention design had resulted in the development of an effective behaviour change intervention.

This paper describes the effect of the *Komboni Housewives* intervention on the four target behaviours: caregiver practice of exclusive breastfeeding of infants 0-5 months-of-age; handwashing with soap after toilet use; correct preparation of ORS; and use of zinc in the home management of childhood diarrhoea. Secondary outcome measures are also reported.

7.3 Research Paper 2

Multiple behaviour change intervention for diarrhoea control in Lusaka, Zambia: a cluster randomised trial

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RESEARCH PAPER COVER SHEET

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SECTION A – Student Details

Student	Catherine Elizabeth Greenland
Principal Supervisor	Dr. Val Curtis
Thesis Title	Unpacking the Black Box: Theory-Based Design & Evaluation of a Multiple Behaviour Change Intervention to Control Diarrhoeal Disease

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	Lancet Global Health		
When was the work published?	December 2016		
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For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	With input from co-authors, I designed the trial, led the data collection team and performed data analysis. I drafted this research paper and all co-authors contributed to its content. I responded to peer-review comments.

Student Signature: _____ **Date:** 14th Feb 2017

Supervisor Signature: _____ **Date:** 14th Feb 2017

Multiple behaviour change intervention for diarrhoea control in Lusaka, Zambia: a cluster randomised trial

Katie Greenland, Jenala Chipungu, Val Curtis, Wolf-Peter Schmidt, Zumbe Siwale, Mweetwa Mudenda, Joyce Chilekwa, James J Lewis, Roma Chilengi

Summary

Background Effective prevention and control of diarrhoea requires caregivers to comply with a suite of proven measures, including exclusive breastfeeding, handwashing with soap, correct use of oral rehydration salts, and zinc administration. We aimed to assess the effect of a novel behaviour change intervention using emotional drivers on caregiver practice of these behaviours.

Methods We did a cluster randomised controlled trial in Lusaka Province, Zambia. A random sample of 16 health centres (clusters) were selected from a sampling frame of 81 health centres in three of four districts in Lusaka Province using a computerised random number generator. Each cluster was randomly assigned 1:1 to either the intervention—clinic events, community events, and radio messaging—or to a standard care control arm, both for 6 months. Primary outcomes were exclusive breastfeeding (self-report), handwashing with soap (observation), oral rehydration salt solution preparation (demonstration), and zinc use in diarrhoea treatment (self-report). We measured outcome behaviours at baseline before start of intervention and 4–6 weeks post-intervention through repeat cross-sectional surveys with mothers of an infant younger than 6 months and primary caregivers of a child younger than 5 years with recent diarrhoea. We compared outcomes on an intention-to-treat population between intervention and control groups adjusted for baseline behaviour. The study was registered with ClinicalTrials.gov, number NCT02081521.

Findings Between Jan 20 and Feb 3, 2014, we recruited 306 mothers of an infant aged 0–5 months (156 intervention, 150 standard care) and 343 primary caregiver of a child aged 0–59 months with recent diarrhoea (176 intervention, 167 standard care) at baseline. Between Oct 20 to Nov 7, 2014, we recruited 401 mothers of an infant 0–5 months (234 intervention, 167 standard care) and 410 primary caregivers of a child 0–59 months with recent diarrhoea (257 intervention, 163 standard care) at endline. Intervention was associated with increased prevalence of self-reported exclusive breastfeeding of infants aged 0–5 months (adjusted difference 10·5%, 95% CI 0·9–19·9). Other primary outcomes were not affected by intervention. Cluster intervention exposure ranged from 11–81%, measured by participant self-report with verification questions. Comparison of control and intervention clusters with coverage greater than 35% provided strong evidence of an intervention effect on oral rehydration salt solution preparation and breastfeeding outcomes.

Interpretation The intervention may have improved exclusive breastfeeding (assessed by self-reporting), but intervention effects were diluted in clusters with low exposure. Complex caregiver practices can improve through interventions built around human motives, but these must be implemented more intensely.

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See **Comment** page e881

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Introduction

Seemingly simple, inexpensive interventions that can prevent most diarrhoea morbidity and mortality have been available for many years, yet diarrhoea remains one of the biggest killers of children worldwide.[1]

In 2009, WHO and the United Nations Children's Fund (UNICEF) called for implementation of the 7-point plan, a comprehensive strategy for diarrhoea control based on seven curative and preventive interventions: fluid replacement to prevent diarrhoea, typically through use of low-osmolarity oral rehydration salts (ORS); treatment with zinc; water, sanitation, and hand hygiene interventions; rotavirus and measles vaccination; exclusive breastfeeding; and vitamin A supplementation.[2] The widespread adoption of diarrhoea control measures could prevent 95% of child mortality from diarrhoea by 2025.[3] These control measures could subsequently reduce susceptibility to pneumonia [4] and undernutrition,[5] and improve cognitive development.[6] In reality, these benefits are limited because of low coverage and uptake of these interventions, particularly in those most at risk.[3]

Exclusive breastfeeding is associated with reduced childhood diarrhoea mortality and morbidity,[7] and quicker recovery during illness,[8] particularly when infants are exclusively breastfeed for the first 6 months of life,[9] yet fewer than 40% of infants aged 0–5 months are breastfeed exclusively.[10] Handwashing with soap can prevent up to 40% of diarrhoeal episodes, yet only about

Research in context

Evidence before this study

Existing knowledge on drivers of each behaviour and the effectiveness of community-based intervention strategies to influence them was considered through literature search, review of previous work in Zambia, and a framing workshop held in December, 2012, which brought together all sources of information to map what was known and not known about the target behaviours ahead of formative research conducted before intervention development. This process followed the Behaviour Centred Design Approach. Emotional drivers have been previously used in public health interventions, but to our knowledge affiliation and disgust motives have not been used to instigate change in the other targeted behaviours.

Added value of this study

This theory-based, multi-faceted intervention brought a fresh approach to the ongoing challenge of behaviour change that continues to impede diarrhoeal disease control programmes in Africa and elsewhere. The intervention tested here succeeded in improving self-reported rates of exclusive breastfeeding of infants aged 0–5 months, despite low intervention exposure. In areas where exposure was higher the intervention appeared to be more effective across other behaviours. Collectively, this suggests that the intervention might have succeeded in attaching a new motivation to breastfeeding behaviour and, if adapted and delivered in a way that achieves greater reach in a community, this approach could be used to improve other behaviours too.

Implications of all the available evidence

Clinic interventions on breastfeeding should be complemented by community-based strategies, usually involving peer-to-peer individual or group counselling sessions. This trial suggests that a package that also includes elements of the Komboni Housewives intervention could potentially be more effective. The trial also provides support for increased investment in the development of approaches based on emotional drivers of behaviour.

19% of people worldwide wash their hands with soap after using the toilet.[11] ORS prevents and reverses dehydration caused by diarrhoea,[10] but only a third of diarrhoeal episodes are treated with ORS,[10] and administered ORS might be prepared incorrectly.[12] Zinc is also an effective therapy,[13] but its use is uncommon.[10]

In Zambia, diarrhoea is a major cause of child mortality.[14] 73% of mothers report that they exclusively breastfeed their infants aged 0–5 months, but 39% of infants aged 4–5 months are given complementary foods,[14] a decision that is often influenced by the social environment.[15] Only 13% of homes have both a specific place for handwashing and soap and water available at this location,[14] which suggests suboptimal handwashing practice.[16] The population is familiar with ORS and it is reportedly used to treat 64% of diarrhoeal episodes,[14] but fewer than 30% of ORS solutions are prepared correctly, inhibited by aspects of the physical environment such as difficulty measuring 1 L of water accurately and reluctance to use a whole sachet of salts to make up ORS solution.[17] Zinc is largely unknown by caregivers as a diarrhoea treatment.[17]

The gap between best practice and reality represents a major behaviour change challenge for the public health community. Behaviour is influenced by the physical, social, and biological environment and our conscious and unconscious responses to it through a complex array of interacting and often interdependent factors.[18] Interventions that seek to improve behaviour by manipulating one or more of these factors can be more effective than standard health education.[11,19] To improve intervention science and thereby the effectiveness of behaviour change interventions, innovative, theory-based campaigns need to be developed and rigorously assessed.[20] This is particularly important when interventions are complex and target multiple behaviours for change simultaneously.[21]

We test the hypothesis that an innovative behaviour change campaign targeted at caregivers of children younger than 5 years can improve multiple caregiver behaviours concerning diarrhoea prevention and treatment. We designed a novel intervention to improve multiple behaviours related to diarrhoea prevention and management in Zambia by associating their practice with new motivations elicited through emotional demonstrations and a unifying campaign theme. In this Article, we report the effect of this unconventional campaign on caregiver practice of exclusive breastfeeding, handwashing with soap, and use of correctly prepared ORS and zinc to treat childhood diarrhoea.

Methods

Study design and participants

We did a cluster randomised trial in Lusaka Province, Zambia, between Jan 20 and Nov 7, 2014. Clusters were defined as clinic catchment areas, as the intervention was predominantly delivered at clinics and via community events. 16 clinics were randomly selected from a list of 81 government clinics in three of the four districts of the province. One district was excluded for pragmatic reasons as it is sparsely populated.

The intervention targeted primary caregivers of children younger than 5 years, but the assessment was restricted to two specific populations: mothers of an infant younger than 6 months and primary caregivers of a child younger than 5 years with recent diarrhoea. Diarrhoea was defined by the WHO definition as three or more loose stools within 24 h, or more frequent motions than usual for the

individual.[22] Recent was defined as the last 7 days to reduce recall bias.[23] Baseline and follow-up surveys were independent random samples, as caregivers of children eligible at baseline would not have all been eligible at follow-up. The follow-up sample excluded individuals who had moved into the area since baseline.

Randomisation and masking

Clusters were randomly selected within three strata based on district in a 2:1:1 ratio, resulting in a sample that was half peri-urban (Lusaka district) and half rural (Chongwe and Kafue districts). A statistician unrelated to the study allocated half of the clusters in each district to intervention or control (no intervention, standard care at clinics) using a random number table. Randomisation was done before baseline data collection took place, but cluster allocation was concealed from the study team until after baseline data had been collected.

Participants could not be masked to the intervention. Outcome assessors were not involved in delivering the intervention and were not informed where the intervention had taken place.

Komboni Housewives intervention

Campaign development followed the Behaviour Centred Design approach, a 5-step process for the design and testing of behaviour change interventions: assess what is known and what is not known about the behavioural problem; build on this work by doing formative research on the factors inhibiting and facilitating practice of the target behaviour(s); and create, deliver, and evaluate a theory-based intervention.[24] These steps in themselves are not novel, but the process is a helpful way of ensuring the tested intervention is grounded in theory about the determinants of behaviour.

The formative research was guided by the Evo–Eco theory of behavioural determinants [18] that gives equal weight to understanding how psychological (automated or habitual, motivated, and rationalised) factors and environmental (physical, social, and biological) factors influence behaviour with a view to identifying possible solutions to behavioural problems. This theory was previously used to inform the design of interventions in other settings.[25,26] Formative research revealed that knowledge about good childcare practices was widespread, but handwashing and feeding behaviour were suboptimal, ORS was incorrectly prepared, and awareness of zinc as a treatment was low. Results of the formative research also showed that women seek to avoid being a source of gossip in their community.[15,17] Associating practice of a given behaviour with a new motivation might facilitate behaviour change in an enabling environment and the decision was made to build the campaign around the motive of affiliation, the drive to become an accepted member of a given social group.[27] The aim was to associate practice of the target behaviours with achievement of social approval and imply that the target behaviours were substantively normative.

The campaign, developed with creative agency DDB Iris, centred on a group of women known as Adzimayi Bamu Komboni, meaning housewives of the slum community. This group gossiped about women whose behaviour was believed to deviate from the target behaviours, but they ultimately admitted women into

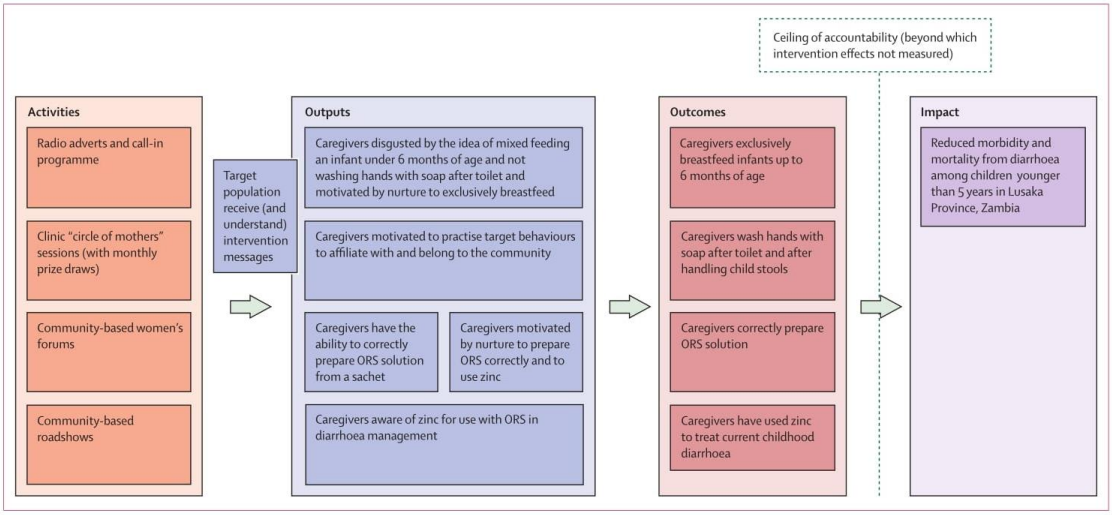

Figure 1: **Simplified Theory-of-Change Model of the Komboni Housewives Intervention**
ORS=oral rehydration salts.

	Target audience	Setting	Implementers	Content	Delivery
Radio adverts and call-in show	Population in target areas, particularly caregivers of children younger than 5 years	Broadcast on three radio stations: Komboni Radio, Radio 1, and Radio 4	Komboni Housewives and radio MCs	Airing of three different spot adverts (EBF, HWWS, ORS+Zinc); similar content to that described in the forum and roadshows skits; call-in shows used as a discussion forum and to amplify the activities of the women's forums (the timing of the shows coincided with the women's forums); discussions scripted around the target behaviours to test the callers' understanding of the intervention messages; jingle about the target behaviours also played	Three times a week for 6 months, with penetration in both intervention and control areas
Komboni Housewives women's forums	About 20 caregivers of children younger than 5 years	Forums held in the community at the home of a host (an intervention recipient)	Komboni Housewives	All four behaviours targeted using skits (featuring the Komboni Housewives gossiping about mothers they believe are not practising the correct behaviours, being proven wrong and welcoming the mother into their group); discussion with question and answer sessions; emotionally engaging demonstrations (designed to evoke feelings of disgust at mixed feeding a baby younger than 6 months and not handwashing with soap, and nurture in relation to incorrect preparation of ORS); and short films featuring the Komboni Housewives (introduced partway through the intervention period); activities were supported by banners, certificates, stickers, a branded bus, and prizes (hats and T-shirts)	One or two forums per day throughout intervention period; rotating between the eight intervention areas
Circle of mothers initiative (with monthly prize draw)	Caregivers of children younger than 5 years (preferentially those with a child presenting with diarrhoea)	At the ORT corner (where ORS solution is traditionally available) or another designated area in the government clinic in each intervention area	Two Neighbourhood Health Committees linked to the clinic in each site	Circle of mothers: content similar to forums designed to be shorter and focused on exclusive breastfeeding and ORS and zinc Prize draws: winner of a hamper selected from all caregivers who attended the clinic session in the previous month; the Komboni Housewives did a mini forum at select prize draws	Every Monday–Friday at clinics in all eight sites Monthly in each site; attended by Komboni Housewives once per site
Roadshows	All community members	Large public space in each site	MCs and Komboni Housewives (featuring a well-known local musician, Afunika)	Large roadshows, one in each intervention area. Similar content to the forums but energised by the presence of the MCs and the presence of Afunika who sang the campaign song, engaged the audience in discussion about the target behaviours; discs featuring the campaign song, hats, and T-shirts were given to those giving correct answers in a quiz	One roadshow in each site

MC=master of ceremonies. EBF=exclusive breastfeeding. HWWS=handwashing with soap. ORS=oral rehydration salts. ORT=oral rehydration therapy.

***Table 1*: Overview of intervention content and delivery schedule**

their social circle (a reward) when it was proven that they were practising the correct behaviours. The motives of disgust (an adaptive mechanism that helps us to avoid disease) and nurture (a natural instinct to protect and care for one's offspring)[27] were also used to drive behaviour change through elicitation of strong emotional responses in connection with the targeted behaviours. All elements were piloted to assess acceptability and comprehension.

The campaign had four components: women's forums delivered in neighbourhoods; roadshows delivered in public gathering spaces; clinic-based circle of mothers sessions with monthly prize draws; and call-in programmes on local radio linked to the forums. Women's forums were small group events in people's homes involving mothers of children younger than 5 years. Roadshows were large gatherings designed to draw the whole community and raise awareness of the campaign. Clinic sessions were small-scale versions of the forums with a focus on ORS and zinc. The radio programmes discussed myths and challenges around the target behaviours and were broadcast in intervention and control areas. The community activities (forums and roadshows) were delivered by a troupe of actors, and pairs of Neighbourhood Health Committee volunteers affiliated with the clinics and already known in the communities delivered the clinic sessions at each clinic. Eligible individuals had the opportunity to attend each event, ranging in duration from 45 min (clinic sessions) to several hours (roadshows). Figure 1 shows a simplified theory of change for the intervention.

For more on the **Komboni Housewives intervention** see http://kombonihousewives.lshtm.ac.uk

The target behaviours were addressed through a combination of role play, skills demonstrations (eg, the correct preparation of ORS), visual, interactive demonstrations designed to evoke strong emotional responses, question and answer sessions, quizzes, video adverts shown on screens, dance, and prize giving. Table 1 provides an overview of intervention content and delivery during the 6-month implementation period. The Komboni Housewives intervention ran from mid-March to mid-September, 2014.

Outcomes

This is an assessment of a complex intervention with analyses of endpoints measuring multiple behaviours. As such, we designated one endpoint as primary for each of these behaviours (and others as secondary). We defined four primary outcomes: exclusive breastfeeding of infants aged 0–5 months (by self-report); handwashing

after risk of contact with faeces (by structured observation); the correct preparation of oral rehydration solution (by demonstration); and the use of zinc to treat childhood diarrhoea (by self-report). No health outcomes were measured.

In accordance with WHO definitions, exclusive breastfeeding was defined as a child having received no food or drink besides breastmilk, vitamins, or medicines in the preceding 24 h.[28] The number of faeces-related events associated with handwashing with soap was measured by direct observation.[29] ORS preparation was observed using a structured checklist, with correctly-mixed solution defined as the combination of a whole sachet of ORS with 1 L of clean (boiled or chlorinated) water. Zinc use referred to reported treatment of current childhood diarrhoea with zinc.

Secondary outcomes were exclusive breastfeeding of infants 0–2 months; predominant breastfeeding of infants aged 0–5 months (consumption of water and water-based drinks or fruit juice alongside breastmilk, vitamins, and medicines);[28] handwashing with soap at key times (associated with food handling and risk of contamination with faeces); use of soap on the occasions hands are washed; presence of ORS sachets within the home; treatment of the current episode of diarrhoea with ORS; previous use of zinc; and awareness of zinc as a diarrhoeal treatment.

Sample size

The required sample size was calculated for each of the primary outcomes and the largest sample size needed to detect a 20% absolute increase in the prevalence of correct preparation of ORS (from 30% to 50%) with 80% power, a two-sided alpha of 0·05 and an intraclass correlation coefficient (ICC) of 0·01 [25] was adopted. Assuming a cluster size of 20 individuals resulted in a design effect of 1·19 and 120 individuals, in six clusters per group. To allow for the uncertainty in the ICC and possibly lower effect sizes, we increased the sample size by two clusters per arm, resulting in eight clusters per arm with 160 individuals per group. To improve the scope for process documentation and secondary analyses an additional ten eligible individuals were recruited in each intervention cluster at follow-up.

Procedures

Breastfeeding and handwashing outcomes were assessed in mothers of infants younger than 6 months and ORS and zinc outcomes were measured in primary caregivers of a child younger than 5 years with recent diarrhoea. Outcomes were measured through cross-sectional surveys done at baseline and at follow-up, 4–6 weeks after the end of the intervention. Handwashing outcomes were measured through a 3 h period of structured observation (from 0600 h to 0900 h, or 1100 h to 1400 h) done before survey administration. Data were also collected on sociodemographic variables and water and sanitation facilities. Exposure to any components of the Komboni Housewives was also captured at follow-up. Surveys were piloted and administered in the preferred language of the participant (usually Nyanja or English).

We based sampling in each peri-urban cluster on the so-called fried egg design,[30] whereby sampling was restricted to a defined sampling area around each clinic (the egg yolk) and not the full catchment area. We mapped and divided the area into four segments, with recruitment within each segment beginning at a randomly selected starting point and thereafter following a random walk according to a protocol to guide the direction of this walk. We left a gap of three households (one in rural areas) each time an eligible individual was identified. We sought basic demographic information from eligible non-participants, and we revisited eligible houses if the caregiver was absent or busy.

Enumerators were all female, educated beyond high school, and familiar with doing research studies. They underwent a week of training including classroom and practical sessions.

Ethics and consent

We obtained written informed consent or a witnessed thumbprint from all participants and eligible non-participants who volunteered demographic data in the baseline or endline surveys. The study protocol was approved by the ethics board at the London School of Hygiene & Tropical Medicine (approval number 6493) and by the University of Zambia Biomedical Research Ethics Committee (ref 001-09-13). The Ministry of Health also gave permission for the study.

Statistical analysis

Data were double entered into Epi Data 3.1 and cleaned using Stata 14 (StataCorp 2015, College Station, TX, USA). We checked discrepant entries against original paper surveys and did consistency checks. We recoded variables and did principal component analysis to compute wealth quintiles.[31]

We did the primary analysis on an intention-to-treat basis. We computed cluster summaries for each behavioural outcome as the means of cluster means.[30] We used an unpaired *t* test to compare crude proportions between study groups and compute confidence intervals. We calculated the ICC for each behavioural outcome. The analysis plan prespecified that analyses were adjusted for baseline measures of each respective outcome. We did not adjust for multiple testing, as any change in a target behaviour was assessed separately.[32]

We used standard methods for trials with few clusters to analyse all endpoints,[30] giving each cluster equal weight, and followed the two-step approach recommended by Hayes & Moulton to adjust for cluster baseline values of each outcome measure.[30] This approach involved logistic regression of binary behavioural outcomes and baseline levels of behaviour

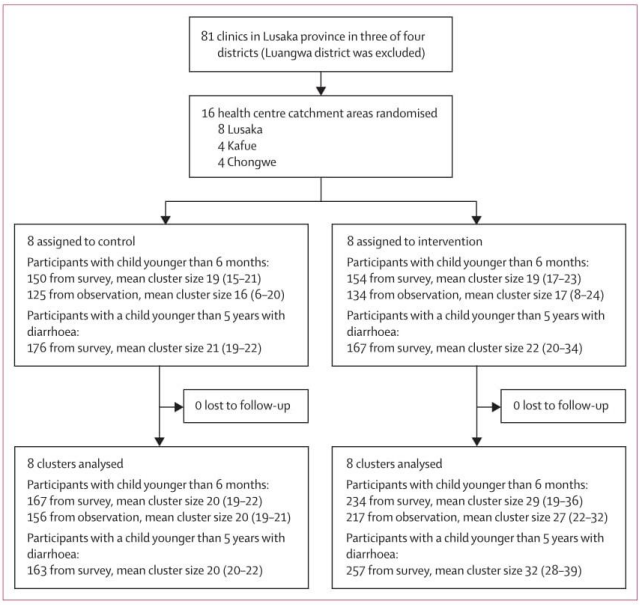

Figure 2: **Trial profile**

using individual household data, ignoring clustering and treatment arm allocation, and subsequently comparing cluster residuals. We adjusted breastfeeding rates for infant age (prespecified primary analysis). We estimated adjusted effect measures and 95% CIs following the approach recommended by Hayes and Moulton, as described previously, replacing cluster proportions with the baseline adjusted residuals and adjusting the p value and 95% CIs by reducing the degrees of freedom by 1. We assessed intervention exposure in all surveyed households in intervention and control clusters at the close of each survey. We defined intervention exposure as self-reported attendance at one or more of the following intervention components: women's forum; clinic circle of mothers session or prize draw; or roadshow. We asked verification questions requiring the participant to provide more detail about the event attended. As variability in exposure to the intervention was anticipated, we planned subgroup analysis based on exposure. Intervention clusters were grouped into high exposure (more than 30% of a cluster) and low exposure (less than 30% of a cluster) post hoc. We designed the clinic sessions to be shorter to avoid burdening caregivers with an ill child, so these sessions did not contain handwashing messages; the exposure variable for handwashing outcomes was modified accordingly. We measured exposure to the radio show, but did not adjust for this. The study was registered with ClinicalTrials.gov, number NCT02081521.

See Online for appendix

Role of the funding source

The funders of the study reviewed the study protocol but had no role in the choice of study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Baseline data were collected in January–February, 2014, and endline data were collected in October–November, 2014 (figure 2). Baseline profiles of participants were similar for most sociodemographic characteristics and prevalence of behaviours, though there were differences between the study groups in both survey profiles with respect to educational level, employment status, prevalence of shared sanitation, awareness of zinc, and use of ORS and zinc (table 2). Only 13 eligible individuals declined to participate in the study at either baseline or endline.

The mean age of infants included in the survey of infants younger than 6 months at follow-up was similiar between study arms (control 3·0 months; intervention 2·9 months). 92% of birth dates in each arm were verified using the health card for children younger than 5 years. Breastfeeding was initiated after birth by almost all mothers (98% control *vs* 99% intervention). There was good evidence that the proportion of mothers practising exclusive breastfeeding of infants aged 0–5 months at follow-up was 11% higher in the intervention arm than in the control arm (95% CI 0·9–19·9, table 3).

Figure 3 presents age-specific prevalence of exclusive breastfeeding at follow-up; exclusive breastfeeding was more common in the intervention arm than in the control arm in all but one age group.

Despite differences in baseline levels of behaviour, the measured change in exclusive breastfeeding rates was seen in both rural and urban areas (appendix).

49 (12%) of 394 households did not have any soap in the home for handwashing. 1255 events involving risk of contact with faeces (after toilet, or after cleaning up or disposing of a child's stool, n=268) or food handling (preparation, eating or feeding a child, n=987) were recorded in 373 households during observation of female caregivers at follow-up. Handwashing with soap was observed on 32% of faeces-related events (primary outcome) in the intervention group and 28% of events in the control group, no different from baseline (adjusted difference 4%, 95% CI –19·3 to 27·8). No difference was reported in rates of handwashing in relation to food handling (5·6% intervention *vs* 6·8% control, adjusted difference –1·3%; –5·7 to 3·2), or at any key time for handwashing (table 3). Use of soap or soapy water on occasions when hands were washed was also unchanged. Handwashing rates between the two groups did not differ by educational level or wealth quintile (data not shown).

Only four participants at follow-up declined to prepare ORS. There was weak evidence that ORS was correctly

	Caregiver of child younger than 6 months (N=306)				Caregiver of child younger than 5 years with diarrhoea (N=343)			
	N	Control (n=150)	N	Intervention (n=156)	N	Control (n=167)	N	Intervention (n=176)
Household size, median (IQR)	146	5 (4–7)	153	5 (4-7)	167	6 (4–7)	176	5 (4–7)
Age of caregiver in years, median (IQR)	141	27 (23–33)	149	26 (21–31)	159	28 (24–34)	169	26 (22–32)
Age of eligible child in months, median (IQR)	150	3 (3–4)	154	4 (3-5)	160	27 (16–40)	163	21 (15–32)
Resident at address for 3 months or less	150	13 (8%)	154	20 (13%)	167	16 (10%)	176	24 (14%)
Married or living with partner	149	117 (79%)	152	126 (83%)	165	130 (79%)	171	124 (73%)
Highest education level of caregiver								
None	148	9 (6%)	151	5 (3%)	164	5 (3%)	176	12 (7%)
(Some) primary	148	59 (40%)	151	51 (34%)	164	77 (47%)	176	75 (43%)
(Some) secondary	148	59 (40%)	151	85 (56%)	164	67 (41%)	176	80 (46%)
Higher education	148	21 (14%)	151	10 (7%)	164	15 (9%)	176	9 (5%)
Employment status of caregiver								
None	149	100 (67%)	154	122 (79%)	165	113 (69%)	176	143 (81%)
Part-time	149	32 (22%)	154	25 (16%)	165	44 (27%)	176	25 (14%)
Full-time	149	17 (11%)	154	7 (5%)	165	8 (5%)	176	8 (5%)
Asset-derived wealth quintile*								
Poorest	146	46 (35%)	144	41 (32%)	137	46 (34%)	135	46 (34%)
Middle	146	42 (32%)	144	45 (35%)	137	46 (34%)	135	48 (36%)
Least Poor	146	44 (33%)	144	42 (33%)	137	45 (33%)	135	41 (30%)
Household shares sanitation facility	141	70 (49%)	146	105 (72%)	147	90 (61%)	164	109 (67%)
Number of clusters	..	8	..	8	..	8	..	8
Number of individuals per cluster, mean (SD)	..	19 (2·2)	..	19 (2·0)	..	21 (1·0)	...	22 (4·9)
Ratio of urban to rural clusters	..	1:1	..	1:1	..	1:1	..	1:1
Behaviours								
Infants 0–5 months exclusively breastfed	150	45% (20.7)	156	39% (10.1)	..	..	..	..
Hands washed with soap†	189	22% (14·7)	224	25% (15·8)	..	..	..	..
Caregivers preparing ORS correctly	..	..	..	..	146	34% (15·8)	151	33% (13·5)
Diarrhoeal episodes in children younger than 5 years given ORS	..	..	..	..	151	58% (19·2)	158	69% (16·1)
Diarrhoeal episodes in children younger than 5 years given zinc	..	..	..	..	164	5% (6·4)	168	9% (10·7)
Caregivers who have heard of zinc	..	..	..	..	166	16% (9·4)	170	25% (18·4)
Caregivers who have ever used zinc	..	..	..	..	164	8% (11·0)	168	12% (11·6)

Values for individual variables are numbers (%) or median (IQR), and values for cluster variables are mean proportions (SD). ORS=oral rehydration salt solution. *Derived from principal component analysis of 13 household assets (ownership of home, television, mobile telephone, land for farming, non-domestic animals, car, fridge, freezer, bicycle, radio, water tap inside the home, electricity, flush latrine) and material of structure (cement *vs* mud floor, cement or brick *vs* mud wall). †Hands washed with soap or soapy water after toilet, or after cleaning up or disposing of a child's stool, as mean % of all toilet and child defecation events. Handwashing outcomes measured by observation of 681 events in 125 households in the control group and 913 events in 134 households in the intervention group. All behaviours measured as described in the text.

***Table 2*: Baseline characteristics of participants in the two study populations by intervention allocation**

prepared more frequently in the intervention group than the control group (49% *vs* 38%, adjusted difference 13%; –0·5 to 25·7, table 3). Observation of ORS preparation revealed errors mostly concerning the measurement of 1 L of water, with only 139 of 247 participants in the intervention group and 70 of 163 participants in the control group doing this correctly at follow-up (adjusted difference 14%, –1·9 to 29·0, p=0·08; data not shown). The intervention had no effect on reported use of ORS to treat diarrhoea or prevalence of storage of ORS at home (table 3).

Participants in the intervention groups were no more likely to have used zinc to treat current diarrhoea than were those in the control group (adjusted difference 3%, –6·6 to 12·9; p=0·50). The proportion of participants who had ever used zinc increased by 9%, but confidence intervals were wide (95% CI –3·1 to 20·7).

Awareness of zinc as a diarrhoea treatment was substantially higher in the intervention group (25% higher, 11·0–39·1; table 3), an indication that individuals exposed to the intervention had retained this message.

	Control N, % (SD)	Intervention N, % (SD)	Unadjusted effect size (95%CI)	Unadjusted effect p value	Adjusted effect size (95%CI)	Adjusted effect p value
Exclusive breastfeeding						
Exclusive breastfeeding of infants aged 0–5 months	161, 50·5% (12·7)	234, 60·9% (10·7)	10·4% (–2·2 to 23·0)	0·10	10·5% (0·9 to 19·9)	0·03
Handwashing with soap						
Handwashing with soap after risk of contact with faeces*	128, 28·4% (17·7)	130, 32·2% (25·8)	3·8% (–20·0 to 28·5)	0·74	4·2% (–19·3 to 27·8)	0·71
Oral Rehydration Salts						
Caregivers able to correctly prepare ORS	163, 37·6% (12·1)	247, 49·0% (4·9)	11·5% (–2·6 to 25·4)	0·10	12·6% (–0·5 to 25·7)	0·06
Zinc						
Current diarrhoeal episodes in children younger than 5 years treated with zinc	165, 16·3% (9·9)	248, 19·4% (8·2)	3·1% (–6·6 to 12·8)	0·49	3·2% (–6·6 to 12·9)	0·50
Exclusive breastfeeding						
Exclusive breastfeeding of infants aged 0–2 months	75, 67·0% (27·8)	119, 79·3% (17·6)	12·2% (–12·7 to 37·1)	0·31	13·6% (–8·6 to 35·8)	0·21
Predominant breastfeeding of infants aged 0–5 months	161, 61·8% (16·2)	234, 73·9% (10·2)	12·1% (–2·4 to 26·7)	0·09	11·7% (1·2 to 22·2)	0·03
Handwashing with soap						
Handwashing with soap at key times†	498, 12·8% (7·4)	694, 11·0% (5·9)	–1·8% (–8·9 to 5·3)	0·60	–1·7% (–8·8 to 5·4)	0·62
Soap use on occasions when hands are washed‡	399, 29·4% (10·7)	543, 30·0% (9·8)	0·5% (–10·4 to 11·5)	0·92	0·5% (–11·4 to 10·5)	0·93
Oral rehydration salts						
ORS sachet(s) present within the home	101, 33·7% (16·8)	145, 39·8% (12·9)	6·1% (–9·9 to 22·1)	0·43	6·4% (–7·7 to 20·4)	0·35
Current diarrhoeal episodes in children younger than 5 years treated with ORS	169, 57·8% (13·3)	259, 54·7% (6·6)	–3·1% (–14·4 to 8·2)	0·56	–3·2% (–14·5 to –8·0)	0·55
Zinc						
Caregivers have heard of zinc	169, 32·5% (11·9)	259, 61·2% (14·3)	28·6% (14·5 to 42·8)	<0·001	25·1% (11·0 to 39·1)	0·002
Caregivers have ever used zinc to treat diarrhoea in children younger than 5 years	165, 19·4% (13·4)	248, 30·5% (11·9)	11·1% (–2·5 to 24·7)	0·10	8·8% (–3·1 to 20·7)	0·13

ORS=oral rehydration salt solution. *After toilet, or after cleaning up or disposing of a child's stool. †Before handling food (before preparing or eating a meal, or before feeding a child), or after risk of contact with faeces (after toilet or after cleaning up or disposing of a child's stool. ‡Proportion of occassions (key times or other time) when hands were observed to be washed that were accompanied by soap use.

***Table 3*: Effect of the intervention on behavioural outcomes**

In total, 99 (38%) of 259 caregivers of children younger than 5 years with diarrhoea and 95 (41%) of 234 mothers of children younger than 6 months in the intervention group were exposed to at least one face-to-face intervention component. A third of these individuals in each survey attended more than one component. Four control group survey participants reported having attended an intervention event. Self-reported intervention exposure varied considerably between intervention clusters, ranging from 11–81%. Adjusted prevalence differences of the primary outcomes for all four behaviours were 8–16% higher when high exposure intervention clusters were directly compared with control clusters, (table 4, figure 4). Previous use of zinc in high exposure clusters was also higher than in control clusters (adjusted difference 17%, 95% CI 13·2–31·3, p=0·02).

Reported exposure to the Komboni Housewives radio show was higher in the intervention group than in the control group (30% *vs* 16% in children younger than 5 years, 38% *vs* 24% in children younger than 6 months). Excluding control group individuals who had heard the

radio show did not greatly alter cluster prevalence of the target behaviours in the control group.

Discussion

The effect assessment of the innovative Komboni Housewives multiple behaviour change campaign in Lusaka Province, Zambia revealed that the intervention had a positive effect on exclusive breastfeeding of infants aged 0–5 months. The intervention also succeeded in raising awareness of zinc as a diarrhoea treatment, a prerequisite for use. There was weak evidence in support of an improvement in caregiver ability to prepare ORS solution. The intervention did not increase the use of ORS and zinc to treat diarrhoea or handwashing with soap. The trial further highlights some of the challenges associated with assessing complex behaviour change interventions, such as effect dilution due to limited intervention coverage and the potential of bias due to the use of self-reported outcomes and reactivity under direct observation of participants.

The extent to which we interpret the trial findings as evidencing intervention success depends on the amount of change we consider sufficient to conclude that an intervention has worked. As the relationships between practice of each of the target behaviours and diarrhoea morbidity and mortality are well established, an intervention that improves any of these risky practices could have potentially important implications. The intervention was associated with important changes in the primary outcomes for two of the four behaviours when analysis was restricted to clusters where intervention exposure was higher, suggesting that this approach deserves further development.

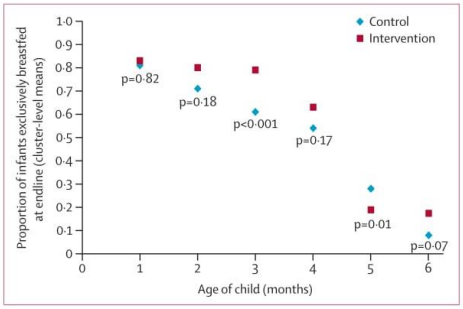

Figure 3: **Proportion of infants exclusively breastfed at follow-up, by age and trial group**

Peer individual and group counselling interventions have successfully improved breastfeeding exclusivity in a range of low-income settings.[33] These interventions are often implemented by community health workers via the clinic, and few trials have assessed community initiatives.[34] This trial adds to this body of evidence and suggests that this approach potentially offers a sustainable community-based intervention that could complement peer support and counselling.

Use of ORS did not increase as a result of the intervention, but there was weak evidence that skill in making it correctly did increase. Few high-quality studies exist on the effectiveness of ORS promotion strategies so it is difficult to position these findings within the wider literature;[35] nonetheless, co-promotion of ORS and zinc can enhance ORS uptake [36] and this did not take place in our study. It is possible that the levers for change for correct ORS preparation were stronger than those used to promote its use. Diarrhoea severity and access to manufactured ORS and zinc might have also influenced caregiver actions.

The intervention succeeded in raising awareness of zinc. Use of zinc to treat current diarrhoea did not increase in areas where the intervention was more intensively delivered, but the prevalence of ever having used zinc to treat childhood diarrhoea did improve. Awareness of zinc as a treatment for diarrhoea is an important first step, because caregivers often prefer to use medicines they know and trust.[17] Low quality data on zinc supply prohibit

	Control clusters (N=8) %, (SD)	Low exposure clusters (N=4) %, (SD)	Low exposure unadjusted effect size (95% CI)	Low exposure adjusted effect size (95% CI)	High exposure clusters (N=4) %, (SD)	High exposure unadjusted effect size (95% CI)	High exposure adjusted effect size (95% CI)
Exclusive breastfeeding 0–5 months	50·5% (12·7)	57·8% (12·7)	7·3% (–10·0 to 24·6)	12·8% (0·8 to 26·5)	64·0% (8·9)	13·5% (–2·5 to 29·4)	13·8% (2·7 to 24·9)†
Handwashing with soap after risk of contact with faeces*	28·4% (17·7)	17·3% (11·1)	–11·1% (–33·0 to 10·7)	–10·3% (–31·6 to 11·1)	47·1% (29·0)	18·7% (–10·9 to 48·3)	12·4% (–15·6 to 40·5)
Caregivers able to correctly prepare ORS	38·0% (12·4)	44·4% (18·9)	6·4% (13·6 to 26·4)	8·3% (–9·6 to 26·2)	53·7% (6·2)	15·7% (0·8 to 30·6)†	16·1% (2·4 to 26·7)†
Current diarrhoeal episode in children younger than 5 years treated with zinc	15·6% (9·3)	15·3% (4·2)	0·4% (–11·4 to 10·7)	0·2% (–11·4 to 11·0)	23·5% (9·7)	7·8% (–5·0 to 20·7)	7·8% (–5·1 to 50·7)

Low exposure clusters=15–28% exposure to at least one face-to-face intervention component. High exposure clusters=35–66% exposure. Adjusted for cluster baseline levels of behaviour and, for exclusive breastfeeding only, age of the infant. ORS=oral rehydration salt solution. *After use of toilet, after cleaning up a child's stools. †p<0·05.

Table 4: **Effects of intervention exposure on key behavioural outcomes**

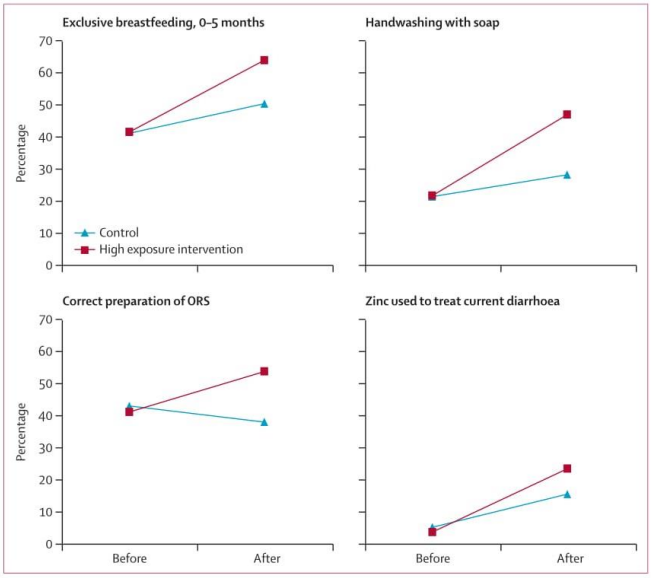

Figure 4: **Comparison of trends in primary outcomes before and after the intervention in control clusters (n=8) and high exposure intervention clusters (n=4)**

assessment of the extent to which availability is likely to have limited uptake, but as zinc availability at clinics and local pharmacies was ensured during the trial but not thereafter this could explain why the number of caregivers who had previously used zinc increased, but zinc use for current episodes did not change. Zinc use in the control group increased from baseline to follow-up. This could be due to exposure to radio messaging (reported by almost one in five5 control group participants), but might also be due to external influence, such as ongoing training of health workers on diarrhoea management and action to improve supply chain.

We did not find an improvement in handwashing behaviour. One key difference between this trial and a previous trial by our group that improved handwashing behaviour in rural India [25] is that the Indian intervention only targeted handwashing practices. Proponents of single behaviour change interventions stress the importance of minimising the number of messages and behaviours to avoid message dilution and overloading of the target population.[37] Those advocating for multiple behaviour change argue that interventions tackling multiple risk factors or disease transmission routes might produce the greatest eventual effect on health in the least resource-intensive manner.[38] Although the Komboni Housewives intervention was only 6 months long and did not explicitly compare delivery of single and multiple interventions, the heterogeneity of intervention effect suggests that some intervention messages might have overshadowed others. It is possible that handwashing messages were less stimulating and novel than the other activities. The results suggest that it might be harder to achieve substantial changes in behaviour when the requisite infrastructure or supplies are absent from households or are kept in an inconvenient place: although 88% of households had soap available for handwashing, 75% of these households kept the soap inside even though hands were washed outside; only 25 of 395 households used a handwashing station when asked to demonstrate how they usually wash hands. Caregivers might need further support through sustained intervention to help them create an enabling physical environment to support handwashing behaviour, [39] but focusing on infrastructure should not preclude efforts to improve important public health behaviours.

The intervention was most successful in clusters where exposure was greatest, which were either rural sites or lower socioeconomic status slum areas. Further exploration of the factors affecting intervention exposure is warranted. It is plausible that the intervention was more successful at changing norms and creating the impression that everybody practises the target behaviours in clusters with higher exposure because messages diffused better through the community. Intervention effects might have been greater if the intervention had continued for longer, allowing time for messages to infiltrate the community.

This study was not powered to analyse effect by component, but exploratory analysis suggests that the high interpersonal contact in the forums was more influential than activities such as the roadshows. If roadshows did not directly influence behavioural outcomes, categorisation of roadshow attendees as exposed might have biased effect estimates towards the null. Furthermore, as individuals could have been exposed to the intervention at any point during the 6-month implementation period, the time between exposure and outcome measurement might have influenced measured effect sizes, particularly for breastfeeding outcomes, where an individual might have been exposed after they had initiated mix-feeding. A cohort design might be preferable in a future study of a similar programme.

The radio element of the Komboni Housewives campaign was included to raise awareness of the intervention target behaviours and to help legitimise community activities. The downside of this is that individuals in the control group were also exposed. A greater proportion of intervention group participants reported exposure to the radio messages, suggesting differential recall bias between study groups. The messages are likely to have been stronger in the intervention areas as the radio show was linked to some of the forums and participants answered questions live on air.

Measurement of behaviour can be prone to social desirability bias in self-report,[40] and in reactivity during observation.[41] Self-reported breastfeeding practices could

lead to over-estimating the effect size as mothers exposed to the intervention might have exaggerated desirable behaviours. However, formative work revealed that the study population was already familiar with messaging on exclusive breastfeeding, so it is not clear that reporting would have differed between study groups. To date, a more robust indicator of breastfeeding behaviour than the WHO indicator with a 24-h recall period that could be used in intervention trials is not available. As outcome assessors were blinded to the intervention and were given only minimal information to enable them to assess exposure, it is possible that individuals who did not recall the intervention well would have been misclassified as unexposed. Effort was made to reduce subjectivity when outcomes were measured by self-report: the survey was preceded by structured observation and questions on infant feeding within the survey were preceded by general questions on the infant's birth and health. If the intervention caused caregivers in the intervention group to modify their behaviour, differential reactivity between study groups could result in over-estimation of the effect of the intervention.

The per-protocol analysis (table 4) needs to be interpreted with caution, as this effectively breaks the randomisation and generally carries a risk of confounding. By adjusting for baseline values of the outcomes we aimed at minimising this risk, but residual confounding cannot be fully excluded in such analysis. The outcome assessment was limited to a fixed area around each clinic (fried egg design). The results of this trial therefore only refer to the population living within the specified area around each clinic. Sensitivity analysis was done to assess whether selection bias was introduced as a result of oversampling in the intervention group. Comparison of equal numbers of intervention and control group participants by removing the extras sampled in each cluster widened confidence intervals but did not appreciably affect the effect estimates.

This trial was a proof of concept study of the Komboni Housewives intervention and hence it was not appropriate to measure health outcomes. As well as showing that a model based on emotional drivers might prompt change in exclusive breastfeeding behaviour, our results also exposed some issues that will need to be addressed before a multiple behaviour change campaign of this nature can be brought to scale in Zambia or anywhere else. The number of target behaviours and messages should be reviewed, the mechanism of change should be explored through process evaluation to learn whether the levers of change were appropriate for each behaviour and the cost-effectiveness of this approach should be assessed.

The Komboni Housewives intervention represents a new and different approach to behaviour change communication and was successful in improving exclusive breastfeeding behaviour and in increasing awareness of zinc. Improvements were also observed in ORS preparation and use of zinc in areas where the intervention reached more widely. Further investigation of factors that influenced these intervention effects and the paucity of effect on handwashing outcomes is warranted. The trial supports the case for continuing to develop novel interventions based on emotional drivers to improve behaviour related to childhood diarrhoea.

Contributors

KG designed the study with input from W-PS, JChip, and RC. The intervention was designed by a creative agency with technical input from VC, JChip, KG, and RC. Study implementation involved KG, JChip, ZS, MM, and JChil. KG analysed the data with input from W-PS and JL. KG drafted the manuscript and all co-authors contributed revisions to the manuscript. KG and JChip had full access to all the data in the study. KG made the final decision to submit for publication.

Declaration of interests

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Chapter 8: Results from the process evaluation

8.1 Overview of chapter

This chapter presents the findings of the process evaluation. The main findings are presented in Research Paper 3 and some additional results on contextual moderators and quantitative data on mediators not included in this paper are reported in Section 8.4.

8.2 Preamble for Research Paper 3

The outcome evaluation revealed that the intervention resulted in significant improvement in only one primary behavioural outcome: reported practice of exclusive breastfeeding of infants 0-5 months-of-age. Exploratory analysis suggested that intervention effectiveness may have been higher in areas where the intervention achieved better coverage. In Research Paper 3, I explore how the intervention was implemented and received. I also propose a mechanism-of-change for the intervention.

8.3 Research Paper 3

Disentangling the effects of a multiple behaviour, multiple component intervention for diarrhoea control in Lusaka, Zambia: a theory-based process evaluation

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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED FOR EACH RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Catherine Elizabeth Greenland
Principal Supervisor	Dr. Val Curtis
Thesis Title	Unpacking the Black Box: Theory-Based Design & Evaluation of a Multiple Behaviour Change Intervention to Control Diarrhoeal Disease

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?			
When was the work published?			
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Implementation Science
Please list the paper's authors in the intended authorship order:	Katie Greenland, Jenala Chipungu, Joyce Chilekwa, Roma Chilengi, Val Curtis
Stage of publication	Not yet submitted

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I designed the process evaluation with input from co-authors. I designed data collection tools, collected some of the data, performed data analysis and drafted this manuscript. All co-authors have contributed to the content of this draft.

Student Signature: _____ **Date:** 14th Feb 2017

Supervisor Signature: _____ **Date:** 14th Feb 2017

Abstract

Background: The *Komboni Housewives* intervention tested a novel strategy employing motives including *affiliation* and *disgust* to improve caregiver practice of four diarrhoea control behaviours: exclusive breastfeeding; handwashing with soap; and correct preparation and use of oral rehydration salts and zinc. The intervention, evaluated in a cluster-randomised trial in sixteen peri-urban and rural communities, resulted in an improvement in exclusive breastfeeding practices, and small changes in the other behaviours in areas with greater intervention exposure. The process evaluation aimed to investigate how the intervention influenced the behavioural outcomes in this context.

Methods: Process data were collected throughout the six-month implementation period and 4-6 weeks afterwards. Qualitative and quantitative data sources included field observation forms, implementation logs, in-depth interviews, focus group discussions and household surveys. Evaluation methods and analyses were guided by the intervention's theory of change and recent evaluation frameworks.

Results: The ease of recruitment and the frequency of intervention activities differed between rural locations and densely-populated, peri-urban slums. Reach was lower than intended and the intensity of implementation was suboptimal: only 11% of the surveyed population attended two or more intervention events. Reach was highest among the poorest and in rural areas. Adaptations made by the implementers affected the fidelity of implementation. Participants were most receptive to the novel disgust and skills-based interactive demonstrations. However, initial *disgust* elicitation was not followed by a change in associated psychological mediators and social norms were not measurably changed.

Conclusions: Achieving high reach and intensity in community interventions is challenging. Further work is required to optimise delivery strategies that are feasible to implement in both peri-urban and rural settings. Better approaches are needed to operationalise and measure the role of subconscious motives in behaviour change interventions.

Background

Whilst there are many excellent and efficacious low cost interventions for the control of childhood illnesses, low rates of caregiver uptake and lack of compliance with recommended treatment strategies limit their effectiveness (Bhutta et al., 2013a, Chopra et al., 2013, Curtis et al., 2009, Omari et al., 2003, ZMOH, 2007, UNICEF, 2012, Ram et al., 2008). The need to improve household behaviours to prevent morbidity and mortality from the major childhood killers, remains evident (Chopra et al., 2013).

In the case of childhood diarrhoea, behaviours such as exclusive breastfeeding and handwashing with soap protect against infection (Black et al., 2008, Kramer et al., 2001, Freeman et al., 2014), whilst treatment outcomes are improved by the use of oral rehydration salts (ORS) and zinc supplementation (Munos et al., 2010, Fischer Walker and Black, 2010). However, despite intervention efforts, caregiver uptake of these practices remains low or inconsistent (Bhutta et al., 2013a, Freeman et al., 2014, UNICEF, 2012, Cai et al., 2012, Hutton and Chase, 2016). Bottlenecks in the ORS and zinc supply chains continue to affect both prescribing behaviour and consumer demand (Chilengi et al., 2016). Promotional strategies to encourage better practices differ widely in their theoretical grounding, content, mode of delivery and effectiveness (Vindigni et al., 2011, Aboud and Singla, 2012, Haroon et al., 2013, Briscoe and Aboud, 2012). This makes it difficult to know which approaches are most worthy of future investment. Innovation in intervention design and in process evaluation tools is still needed, in order to better understand how and why an intervention has worked (or failed) (Coryn et al., 2011, Michie et al., 2009).

The *Komboni Housewives* intervention was designed to encourage change in diarrhoea control behaviours in mothers of children under-five years-of-age in Lusaka Province, Zambia. The intervention promoted four behaviours: the exclusive breastfeeding of infants up to six months-of-age; handwashing with soap after defecation; the correct preparation and use of oral rehydration salts (ORS); and zinc supplementation during home management of diarrhoea. The intervention was designed with the help of the advertising agency *DDB Iris* following the design stages and underlying theory of behaviour laid out in the

Behaviour Centred Design approach (Aunger and Curtis, 2016). This design process also drew on insights from formative research (reported elsewhere (Greenland et al., 2016a)) and the past experience of the investigators (Biran et al., 2014, Curtis et al., 2001, Scott et al., 2008). Intervention concepts and materials were piloted in focus groups with caregivers of children under-five to test comprehension, relevance and acceptability.

The intervention was founded primarily on the insight that people in this populous social context care about their social reputation and seek to avoid becoming the subject of adverse local gossip (the *affiliation* motive (Aunger and Curtis, 2013)). A fictional group of amiable, gossipy local characters known as the *Komboni Housewives* was created and used to suggest that practice of the target behaviours would lead to social approval. Actors playing the *Komboni Housewives* implemented women's forums in the homes of caregivers of children under-five, facilitated radio call-in programmes during these forums, and co-led road shows featuring a famous Zambian musician. Radio programmes were hosted by local DJs who were trained and incentivised to discuss the target behaviours and play campaign radio adverts. These programmes were aired in both intervention and control areas. Daily clinic sessions at the ORT (oral rehydration therapy) corner at health clinics were carried out to target mothers at a hypothesised 'teachable moment' (McBride et al., 2003) (when their child was ill) as a complement to community activities. These sessions were run by volunteer health workers (Neighbourhood Health Committee Volunteers – NHCs) affiliated to the health clinics.

The radio adverts and comical sketches and films delivered in forums and road shows were designed to imply that people watch each other and notice when the target behaviours are not practised. The intervention also utilised other motives (*disgust* and *nurture)* (Aunger and Curtis, 2013) and provided information to enhance knowledge, and to address barriers and misconceptions associated with practice of the target behaviours. An interactive 'Shit and Shake' activity (Sigler et al., 2015) sought to heighten disgust associated with not washing hands with soap after toilet use. Disgust was also used in an interactive 'Baby Tummy' demonstration to encourage exclusive breastfeeding of infants up to six months-of-age through graphic simulation of the contents of the stomach of a mixed-fed baby.

Interactive demonstrations based on the nurture motive were used to convey the functional benefits of administering correctly-prepared ORS, while skill-based knowledge on ORS preparation was boosted through demonstration and behaviour modelling. Information to raise awareness of and demand for zinc was provided during all activities involving ORS.

Visuals from the intervention can be seen in Figure 1 and further details on the intervention content can be found in the paper reporting the trial outcomes (Greenland et al.) and on the campaign website: www.kombonihousewives.lshtm.ac.uk.

[INSERT] Figure 1. Images from the *Komboni Housewives* Intervention

The intervention ran from March to September 2014 in eight peri-urban and rural areas in Lusaka Province, Zambia. The effect of the intervention was evaluated in a cluster-randomised trial with repeat cross-sectional surveys to measure behavioural outcomes (Greenland et al.). Intention to treat analysis found the proportion of infants aged 0-5 months reported to be exclusively breastfed improved from 39% at baseline to 61% 4-6 weeks post-intervention, a baseline and age-adjusted difference of +11% compared with the control group. Zinc awareness was significantly higher in the intervention group (+25%, 95% confidence interval (CI) 11% to 39%). The intervention had no impact on handwashing with soap practices, correct preparation of ORS solution or reported use of ORS and zinc for home treatment of childhood diarrhoea. Exploratory analysis suggested that intervention exposure affected uptake of the target behaviours: all behaviours improved in the four intervention clusters with the highest levels of intervention exposure, although behaviour was only significantly improved for two outcomes (exclusive breastfeeding and the method of ORS preparation).

Theory-driven process evaluation seeks to understand for whom, and under what conditions, an intervention works or fails. If an intervention fails, it can help explain whether it was because the concept and content (i.e. underlying theory) were flawed, or because the intervention was not delivered as it should have been (Oakley et al., 2006). Similarly, if an intervention is effective, it can help to untangle the factors contributing to its success (Moore et al., 2015). The process evaluation

presented here was conducted to i) document how the intervention was implemented across the clusters and different intervention components, ii) describe how the intervention was received by the target population and iii) explore how contextual factors affected both intervention delivery and uptake of new practices. This article reports the findings with respect to these objectives, proposes the mechanism by which intervention delivery, receipt and context contributed to intervention outcomes and discusses the implications of these findings.

Methods

Evaluation Design and Framework

The mixed methods process evaluation of the *Komboni Housewives* intervention was structured around the theory of change (ToC) for the intervention, following the approach developed by de Silva and colleagues (De Silva et al., 2014). Eight process evaluation components relating to intervention delivery, receipt and context were mapped on to this framework. These evaluation domains were primarily drawn from Linnan and Steckler's evaluation framework (Linnan and Steckler, 2002) but also other recent guidance on complex intervention evaluation (Bonell et al., 2006, Grant et al., 2013). The ToC process evaluation framework is shown in Figure 2. The visual representation of the evaluation domains according to categories of 'implementation', 'receipt and mechanism of impact' and 'context' was inspired by recent guidance on process evaluation of complex interventions (Moore et al., 2015).

[INSERT] Figure 2. Process evaluation framework

The implementation of the intervention was assessed through the measurement of four evaluation domains: '*Fidelity'* (the content and quality of the implemented intervention compared with what was intended); '*Dose delivered'* (the number of intended events that were actually conducted); '*Reach'* (the degree to which the intended audience participated in the intervention); and '*Recruitment strategies*' (the procedures used to attract intervention recipients). Intervention receipt and mechanisms of impact were explored through assessment of '*Participant*

Engagement & Responses', (receipt and understanding of key messages, and interaction with the content); '*Acceptability'* (from the perspective of both the recipients and the implementers); and '*Mediators'* (specific behavioural determinants measured along the hypothesised causal pathway). The final domain, '*Context'*, refers to events and influences in the intervention setting and environment that may have encouraged or impeded intervention delivery, receipt and uptake.

Table 1 presents an overview of the research questions defined *a priori* in relation to each evaluation domain, along with the methods that were used to investigate them.

[INSERT] Table 1. Process Evaluation Domains, Research Questions and Methods

Data Collection

Data were collected from the eight intervention areas throughout the six-month intervention period and from all 16 intervention and control areas at endline, 4-6 weeks following termination of intervention activities. Qualitative and quantitative data collection tools were used as described below. All forms were piloted prior to training.

Field Observations

A trained evaluator periodically carried out unannounced field visits throughout the intervention period to observe intervention implementation. A structured reporting form was used to record observed fidelity according to criteria related to adherence to the protocol and the competence of delivery (Carroll et al., 2007, Breitenstein et al., 2010). Technical problems, attendance and perceived participant engagement were also captured. Field observations were conducted at 10 women's forums, 30 ORT corner sessions and at all eight road shows. Radio shows were also audited periodically by evaluators to ensure that they were taking place as intended. Following observation, feedback was provided to implementers to improve intervention fidelity.

Interviews

Semi-structured interviews were held with a random sample of participants following field observations at face-to-face events. These interviews sought to assess understanding and acceptance of the main messages and activities. The nearest recipients to the evaluator at the end of the event were approached and consenting individuals were interviewed in friendship pairs. Individual, semi structured interviews were also carried out with a sample of intervention recipients identified through the endline household survey (described below) to understand how the intervention had influenced behaviour. In total, 29 recipients were interviewed immediately after an event and 17 were interviewed at endline.

Semi-structured interviews were also conducted during and following intervention delivery with the implementers (eight NHC pairs and a *Komboni Housewives* implementer), the creative agency, the implementing agency in charge of the community activations (EXP) and the co-ordinating body (CIDRZ). These interviews explored intervention management, recruitment strategies and challenges, and fidelity of delivery. The head nurse at each intervention clinic was interviewed to understand how the ORT corner sessions affected other clinic activities.

Household Survey

Household surveys with the primary purpose of measuring behavioural outcomes were conducted at baseline and 4-6 weeks after the intervention in all intervention and control areas. Eligible caregivers (with a child under six-months or a child under-five with diarrhoea) were randomly selected within each cluster. Data were also collected on attendance at and recall of intervention activities and on basic demographic variables. Several Likert-type response category questions were included to measure behavioural determinants, or 'mediators' that the intervention aimed to influence. A total of 491 household surveys were carried out in intervention clusters and 330 in control clusters.

Focus Group Discussions

Focus group discussions were also held with intervention recipients and with unexposed individuals in the control arm. Each focus group included six to eight

caregivers of a child under-five. These individuals were identified through the household surveys and were included on a first-come, first-serve basis. Six focus groups were conducted in intervention areas and three in control areas. All focus groups explored social norms and opinions on the importance of gossip and social approval and their role in determining perceptions and practice of the target behaviours. The focus groups held with intervention recipients also explored perceptions of the *Komboni Housewives*. A focus group discussion involving the *Komboni Housewives* actors was carried out to explore deviations from the protocol, recruitment strategies and acceptability.

Activity Logs

Implementers kept records of attendance, the availability of supplies and any challenges or unexpected incidents that affected the event. Attendance was measured by head count shortly after the start of each event. A media monitoring log was used to capture whether the radio call-in programme had taken place and to record any deviations from the intended content.

Data Handling and Analysis

Paper records of field observation forms and implementer logs were entered into MS Excel for analysis. Quantitative data from the endline survey were analysed using Stata 14 (StataCorp 2015, College Station, TX, USA). The proportion of survey respondents who agreed with Likert-type response questions to investigate potential mediators were analysed at cluster level following the two-step approach recommended by Hayes & Moulton (Hayes and Moulton, 2009). All interviews and discussions followed a guide and were voice recorded. Interviews and focus groups were transcribed *verbatim* from recordings and analysed thematically following the six-step method of Braun and Clarke (Braun and Clarke, 2006).

Reach was computed as the proportion of endline survey respondents reporting attendance at one or more face-to-face event. As road shows targeted the whole community, reach was also calculated from the estimated number of attendees at each show divided by the population of the target cluster (which was estimated in a census conducted by the project team). Reach was computed by wealth tertile (poorest, middle and least poor). Wealth was assessed through principal component analysis of 13 household assets and the material of the structure (Vyas

and Kumaranayake, 2006). A matrix was created to organise fidelity data on adherence and delivery competence by target behaviour, intervention component and cluster. A Word Cloud was created to represent participants' reactions to the 'Baby tummy' demonstration using the 'WordItOut' online word cloud generator, which gives greater prominence to words and phrases that are used more frequently.

Results

We present our results by objective and evaluation domain. Objective 1, intervention implementation is described according to *dose delivered, reach, recruitment and fidelity*. Objective 2, intervention receipt is then described in relation to *participant engagement and responses, acceptability and mediators*. Results related to objective 3, *contextual factors* influencing intervention implementation and receipt, are reported together with Objectives 1 and 2.

Intervention implementation

Dose delivered

Table 2 provides a summary of the dose delivered in each cluster and by each intervention component. Overall, 1,386 ORT corner sessions were held with 9,444 caregivers of a child under-five (Table 2). This was fewer than the intended two sessions per site per day (14,000 caregivers) because fewer people attended the rural clinics than we expected. In total, 158 forums were attended by 2,723 women, 96% of whom were from the target population (Table 2). These totals fell short of the planned 194 forums with 4,000 participants, as it proved infeasible to hold more than one forum per day in rural areas. All eight road shows were conducted and were attended by approximately 13,600 men, women and children (Table 2). Radio shows were broadcast in four languages on three radio stations in all intervention and control areas. The shows were aired three times a week and were scheduled to coincide with the forums conducted on those days.

[INSERT] Table 2. Dose Delivered and Reach for Each Intervention Component and Cluster

Reach

Table 2 also indicates the proportion of the target population that was exposed to each intervention component in each cluster, and the proportion of the total population estimated to have attended the road shows. Overall, 253 of 489 (52%) surveyed individuals in the intervention arm had heard of the *Komboni Housewives* campaign, compared with 48 of 330 (15%) control arm participants. The radio show was reportedly heard at least once by 35% of individuals in the intervention arm and 20% in the control arm and achieved the highest reach. Thirty-nine percent of 493 intervention arm participants reported attending at least one face-to-face intervention component. However, the pattern of reach achieved varied by intervention component: 12% attended an ORT corner session and 18% attended a women's forum or road show (Table 2). Only 55 (28%) of these individuals had attended more than one event and only eight individuals attended all three face-to-face events. One in three community members in the intervention areas were estimated to have attended a road show (Table 2).

Differences in reach between the clusters were also striking: cluster-level attendance at one or more face-to-face event ranged from 14% to 66% (Table 2). Although more events were held in densely-populated peri-urban clusters than in harder-to-access rural clusters, the total target population in rural areas was smaller. Consequently, the overall reach in rural areas (+60% in three of four rural clusters) was considerably higher than in peri-urban slums (14-35%). The poorest individuals in each cluster attended more face-to-face intervention components than their more affluent neighbours (Figure 3).

[INSERT] Figure 3. Relationship between socio-economic status and reported intervention attendance

Recruitment strategies

The scattered arrangement of villages and the agricultural workload made it more difficult to recruit mothers in rural areas to attend forums and road shows. Recruitment was least challenging in densely-populated peri-urban areas, although implementers noted that it was harder to recruit women to attend forums in two peri-urban clusters with slightly higher socio-economic status. The radio show

helped to increase the legitimacy of the intervention in the eyes of the target population (Quote 1).

> *Quote 1: "It was such a challenge to do the whole programme and finish it on time in [Clusters 1 and 3]. Basically it was the location; they have no time to waste…. even just bringing the women together was troublesome. That programme on the radio really started changing things. We [also] saw a change after the road shows took place, they really boosted everything. People would start to see us and say: 'those are Komboni Housewives, when are you people coming to our place.' I think it helped us a lot because people recognised us." (Komboni Housewives Implementer)*

The criteria for recruitment at ORT corner sessions were broadened partway through the intervention period to include all caregivers of children under-five presenting at the clinic rather than just those with a child with diarrhoea. As clinic catchment areas could be large (Table 2), many people living outside the trial areas also attended these events. The alteration to the recruitment strategy increased the dose delivered 3-fold in the second half of the intervention period. The quality of the sessions was also inadvertently improved (Quote 2).

> *Quote 2:* "*When it was just the diarrhoea cases the programme wasn't flowing well, but when we included non-diarrhoea cases then it was perfect. The participation was poor when they were few; they would be shy or just concentrating on the child. When there were a lot, one mother would ask a question, the other would rephrase and others would attempt to answer. There was a change in all the corners, you find there was a deeper understanding and the information was spreading vastly though the community. The discussions had improved. When you have a lot of people they even strive to be the one to demonstrate [how to make ORS]." (NHC Implementer).*

Fidelity

The intervention was delivered broadly as intended. However, comparison between intervention components and across clusters revealed some areas where the quality and content of the intervention was compromised (Table 3).

[INSERT] Table 3. Fidelity of delivery

Whilst the intervention was designed to avoid health messaging, field observations revealed that all implementers liked to educate intervention recipients on topics about which they were knowledgeable. This resulted in the inclusion of additional messaging on nutrition and on the importance of cleanliness and handwashing before breastfeeding and preparing ORS at ORT corner sessions. At forums and

road shows, *Komboni Housewives* implementers added demonstrations of handwashing technique, which was not part of the intervention. They also adapted the discussions and skits to try to increase the relevance of the messages for the target audience (Quote 3).

> *Quote 3: "You tell the mother to exclusively breastfeed and then she goes 'what about HIV' and things like that, and others say 'what if the milk isn't coming out, what do you give that child?' They really wanted us to tell them what to feed that child and so we thought we couldn't shut them up so we decided to go off [topic] just to keep them, because you know it is not easy to get a woman's mind to concentrate on what you are saying." (Komboni Housewives Implementer)*

The individual set-up of the clinics affected the location and running of ORT corner sessions. The existing ORT corner was not always conducive to a group meeting and some sessions were moved to out-of-the-way buildings that were hard to find. NHCs also had competing responsibilities that affected the running of the sessions in some clinics. The quality of the demonstrations on ORS preparation and mixed-feeding a baby provided by the *Komboni Housewives* actors was observed to be higher in forums and road shows than at the ORT corner sessions. However, all implementers reported that delivery was affected when there were a lot of distractions (Quote 4).

> *Quote 4: "Since it was an open place people used to move around as you teach so that can make your session bad." (NHC Implementer)*

Three short films featuring the *Komboni Housewives* were played in forums and road shows. A delay in their production held up the road show programmes. Instead of being delivered ahead of the other events, the road shows were delivered towards the end of the intervention period. This adversely affected community awareness and buy-in for the other components of the intervention. The quality of sound and projection of the videos was also sub-optimal at three of the eight road shows.

Intervention receipt

Engagement, responses and mediators

According to the NHCs, it was occasionally challenging to engage mothers of ill children at the clinic sessions before the recruitment strategy changed (Quote 5).

> *Quote 5: "Sometimes it was difficult, especially if a mother came with a baby that had diarrhoea. We would give them ORS at the corner, but even then you would see that the mother would concentrate on the child rather than listen to what we were discussing." (NHC Implementer)*

Participants interviewed immediately post-intervention had generally understood the main messages, but recall of ORS preparation and breastfeeding messages was higher than for the other behaviours. 'Hygiene' was mentioned more frequently than handwashing with soap. Message recall at endline was similar, and quantitative data showed that awareness of zinc as a diarrhoea treatment increased from 25% to 61% as a result of the intervention (adjusted increase of +25% when compared with the control arm).

Intervention recipients responded as intended to the 'Baby tummy' demonstration to promote exclusive breastfeeding: the demonstration evoked strong negative disgust-based reactions, with participants most commonly reporting that they 'felt very bad', were 'disgusted' or thought they would 'vomit' (Figure 4). The baby tummy demonstration was well-remembered at endline, but individuals in the intervention arm were not significantly more likely to agree with the statement *'It is disgusting for me to give my baby food or drink before six months'* than control arm participants (49% vs. 43%, p=0.49).

[INSERT] Figure 4. Word cloud illustrating reactions to the 'Baby Tummy' demonstration to promote exclusive breastfeeding.

Message recall concerning gossiping neighbours (the *Komboni Housewives*) was high and over 90% of survey participants in both study arms agreed that neighbours would gossip about them if they did not take care of their children. However, the cause of gossip (failure to practise the target behaviours) was not so well recalled. Furthermore, those exposed to the intervention were no more likely than control arm participants to believe

that failure to practise the target behaviours incited gossip, or that practice of the target behaviours was the social norm (data not shown). The disgust-based handwashing demonstration was not recalled well at endline and intervention arm survey participants found people who do not wash hands after defecation no more disgusting than control arm participants (28% of respondents in both arms agreed that it is disgusting to shake hands with someone who did not wash their hands after using the toilet).

Acceptability

Implementers appeared to enjoy their work and the status that it afforded, reporting that 'people looked at us like experts'. Intervention recipients confirmed that they regarded the NHCs and *Komboni Housewives* as knowledgeable and credible sources of information. Intervention recipients were similarly keen to be seen to be knowledgeable, frequently citing being equipped to teach other women how to prepare ORS as their favourite aspect of the intervention.

Although mothers were invited in advance to the forums and road shows it was still difficult to sustain interest throughout these longer events. The implementers felt that the events took place at times when women were busy, which affected their motivation and ability to attend the sessions. Nevertheless, in the opinion of the implementers, there was demand for the programme from both the participants (Quotes 6 and 7) and the clinics (Quote 8).

Quote 6: "Other people that stay in far off areas have requested that the programme is extended to reach them so that they also learn how to prepare ORS." (Komboni Housewives Implementer).

Quote 7: "People complained to us that they have not seen the Komboni Housewives. Our plea to you is to roll the programme out to more areas so more people can benefit." (NHC Implementer).

Quote 8: "To be frank, we had a bit of gap [in the services we could provide prior to the intervention]: we had a shortage of staff and so we couldn't really explain to the mothers fully how to give ORS to their children because a nurse had to do it. When the NHCs came they were specifically doing that job unlike a nurse who also had patients waiting for her, so the NHCs were in a relaxed environment and were able to explain to the mothers well." (Head Nurse at an Intervention Clinic).

Several clinic nurses were concerned that raising awareness of and demand for zinc when the supply is currently limited in the public sector presents a sustainability challenge and has the potential to cause tension.

Discussion

The Komboni Housewives campaign was a complex intervention (Craig et al., 2013), comprising multiple interacting components, targeting four disparate behaviours and applied in diverse peri-urban and rural contexts. This innovative intervention was found acceptable by implementers and the target population alike, and clearly engaged target audiences through its novelty, energy and the appealing *Komboni Housewives* characters that were portrayed. However, the intervention achieved mixed results that are hard to interpret from the cluster-randomised trial results alone (Greenland et al., 2016b). The reach and intensity of implementation of the intervention were poor, and behaviour change was limited, except for one reported behaviour (exclusive breastfeeding). Where better reach was achieved, there was an indication that levels of behaviour change were greater, but changes were only significant for breastfeeding and ORS preparation outcomes.

Intervention reach and intensity

Overall, the programme delivered a lower intervention dose than was intended and this affected its reach and intensity, with only 11% of the surveyed target population reporting attendance at two or more intervention events. Radio achieved the best reach (35%), followed by the road shows and forums (both 18%). The reach of ORT corner sessions was lower (12%), but women throughout the clinic catchment area benefited from this intervention. As each intervention component was delivered in different settings and the intervention duration was

short, it is not surprising that relatively few individuals were exposed to the full intervention package. Whilst it is recognised that community-based interventions involving interpersonal communication may have limited ability to achieve the levels of reach achieved through other means (Merzel and D'Afflitti, 2003), the intervention was clearly implemented sub-optimally in many intervention areas.

The main body of the intervention comprised the community forums delivered by the *Komboni Housewife* actors and the clinic-based ORT corner sessions facilitated by the NHCs. Combining facility-based delivery platforms with community-based events is a strategy that has the potential to achieve high intervention coverage (Imdad et al., 2011, Bhutta et al., 2013b). However, more implementers would be required to adequately reach women with a group intervention (such as the women's forums) in densely-populated, peri-urban settings. This would probably make it difficult to maintain implementation fidelity, as observed during delivery of the ORT corner sessions. Furthermore, the sustainability of training actors to deliver these events is questionable. As NHCs are already well-known and respected in the community, and arguably more knowledgeable – albeit less dynamic - than the *Komboni Housewife* actors, a solution may be to train new NHCs to take on this role. Use of community health workers has been shown to be associated with the attainment of high, equitable intervention coverage (Das et al., 2013).

Intervention reach varied by socio-demographic status and cluster, as well as by delivery channel. As differential reach across sub-groups can bias intervention effects and potentially widen health inequalities (Victora et al., 2012), it is encouraging that poorer individuals in each community were more frequently exposed to the intervention (and appeared to be more accepting of the intervention content). The highest levels of reach were observed in rural areas where the target population was smaller and there were fewer alternative sources of entertainment. Even though the total number of individuals reached in peri-urban areas was higher (which has implications for the cost of delivery), the intervention strategy appears to have been more suited to delivery in rural areas.

There is limited consensus on how best to achieve high coverage of public health interventions in low-income countries (Chopra et al., 2012). Further work is required to optimise strategies for the delivery of community interventions so that

they are feasible to implement in both peri-urban and rural settings. Such efforts are likely to require the development and use of appropriate measures of 'implementation strength' in process evaluations so the intensity of delivery required to achieve health gains can be assessed (Hargreaves et al., 2016). There may also be a need to be more realistic about the levels of reach that are achievable in community behaviour change interventions.

Mechanism of change

The intervention produced differential changes in the target behaviours, which suggests that there was some level of programme failure as well as implementation failure. By reviewing the process evaluation findings concerning intervention fidelity, contextual factors affecting recruitment in the geographically diverse clusters and implementer perceptions of the intervention, it was possible to conceptualise some of the ways that intervention implementation affected intervention receipt and uptake of the target behaviours. Figure 5 depicts the proposed mechanisms of change for the *Komboni Housewives* intervention.

[INSERT] Figure 5. Proposed mechanisms by which the intervention and its implementation influenced behavioural determinants and behavioural outcomes

Figure 5 indicates that the central concept of the intervention – *affiliation* – was memorable, but did not change norms. This could be due to the low reach of the intervention, a failure to measure norms effectively, or a failure of the central campaign strategy, which was to imply that the target behaviours are normal, and will be noticed and socially rewarded. It is possible, for example, that in urban areas with low social cohesion (van de Vijver et al., 2017), individuals do not experience a sense of community and hence are less susceptible to a norms-based intervention (McMillan and Chavis, 1986). Although social cohesion is suspected to have been greater in rural areas, the physical distance between individuals living in villages with scattered housing may have meant that the notion that an individual's behaviour would be seen by others was implausible. Norms-based interventions have the potential to be powerful (Cialdini et al., 1991, Cialdini et al., 1990), but designing interventions to change norms remains a challenge. As

injunctive norms – what is commonly approved of and *ought* to be done – may only influence behaviour if they are *salient* for the individual at the time the behaviour takes place (Kallgren et al., 2000). Better ways to trigger intervention recall in the settings where behaviour is enacted are needed.

There is some indication that the interactive and novel components of the intervention were well-received and more readily recalled by the target audience. *Disgust* at mixed-feeding was elicited in response to exposure to the 'Baby Tummy' demonstration, and the intervention improved reported practice of exclusive breastfeeding. However, the intervention group did not find it any more disgusting than the control group to mix-feed a baby. This suggests that either the intervention operated via a mechanism other than *disgust*, or that subconscious, psychological behavioural mediators were not well-measured.

The handwashing component of the intervention also included a demonstration that was designed to elicit disgust (the 'Shit and Shake' activity). However, neither behavioural mediators, nor behaviour itself, changed significantly as a result of exposure to this activity. Formative research findings (unpublished) indicated that the target population were tired of handwashing campaigns. The low implementation fidelity and limited recall of intervention messages by intervention recipients suggest that handwashing messages were indeed unattractive to both implementers and recipients. It is possible that they also received less attention because they were delivered alongside other, more innovative, content. The formative research also revealed that water, soap and handwashing infrastructure were rarely found together in a convenient place for handwashing, so handwashing behaviour change may also have been limited by the lack of facilities (Dreibelbis et al., 2013, Hulland et al., 2013, Luby et al., 2009, Aunger et al., 2010, Curtis et al., 2009). It is also possible that handwashing competed with other more pressing needs in the lives of the target population (Langford and Panter-Brick, 2013). However, due to the low implementation fidelity, it is not possible to determine conclusively why the intervention failed to change handwashing behaviour.

The intervention succeeded in enhancing skill in ORS preparation through information provision, and performance-based demonstration and behaviour modelling (Briscoe and Aboud, 2012, Michie et al., 2013, Aunger and Curtis, 2016).

An unanticipated consequence of this activity was that increased knowledge of a practical, childcare-related skill impacted positively on the intervention's acceptability to the target population (see Figure 5). As this intervention component was not technically difficult to deliver, it could be easily adapted and used in other settings. Zinc use, however, was constrained by the limited supply. It is not possible to determine whether increased *awareness* of zinc would have translated to increased *use* of zinc if supply had been widely available at the time of measurement of intervention outcomes. Nor is it possible to know whether use of zinc would have also driven the uptake of ORS – which did not improve, despite improvements in the preparation of ORS solution (Greenland et al., 2016b) – as has been demonstrated elsewhere (Lenters et al., 2013).

Across the whole intervention, adaptations made by the implementers caused the intervention messages to lose some of their simplicity, which in turn may have affected message potency (Sweet and Fortier, 2010). Interventions targeting multiple behaviours need to convey clear messages in a consistent way across intervention components which can be challenging to manage. Although limited research has been carried out to assess whether interventions targeting multiple behaviours have more success if the behaviours are targeted sequentially rather than simultaneously (Hyman et al., 2007), such an approach could reduce the potential for message dilution.

Limitations

It is not possible to discount the possibility that the interpretation of process data was influenced by knowledge of the trial's outcomes, since data from the outcome evaluation were analysed ahead of process evaluation data (Moore et al., 2015, Oakley et al., 2006). However, this decision allowed trial outcomes to be reported sooner and allowed us to direct the analysis of process data towards the outcomes of interest.

The process evaluation was intended to produce a comprehensive assessment of the mechanisms of change. However, lack of heterogeneity in response to the Likert-type response questions on gossip, social approval, norms and the emotional motivators meant that these data could not be utilised as planned in

mediation analysis (MacKinnon et al., 2007). This limited our ability to explore the role of the hypothesised 'active ingredients' of the intervention.

Conclusions

Achieving high reach and intensity of implementation in community interventions is challenging and further work is required to optimise delivery strategies that are feasible to implement in both peri-urban and rural settings. Development of a testable theory of change can help to ensure that theory-based interventions have clear hypothesised pathways to change. Using this theory of change to guide the process evaluation aids the investigation of the extent to which intervention implementation, programme theory and contextual factors influenced intervention outcomes. However, low intervention reach makes it difficult to draw firm conclusions about the role of *affiliation* and *disgust* motives in behaviour change interventions. Better approaches are needed to operationalise and measure the role of these subconscious motives in behaviour change interventions.

List of abbreviations

NHCs – Neighbourhood Health Committee (Volunteers)
ORS – Oral rehydration salts
ORT – Oral rehydration therapy
ToC – Theory of change

Declarations

Ethics approval and consent to participate

We obtained written informed consent or a witnessed thumbprint from all participants, regardless of the method. The study protocol was approved by the ethics board at the London School of Hygiene & Tropical Medicine (approval number 6493) and by the University of Zambia Biomedical Research Ethics

Committee (ref 001-09-13). The Ministry of Health also gave permission for the study.

Consent for publication

Consent forms specifically stated the following: *'I give permission for things that I say during interviews or focus groups to be quoted anonymously to communicate the findings of this research, to analyse this research and for teaching purposes. Information about the study could potentially be seen by researchers and students in Zambia and beyond and by health professionals and decision-makers in Zambia and beyond.'* To make this abstract concept more accessible, it was also explained to the participants verbally.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

KG conceived the study and KG and JC1 (Jenala Chipungu) designed the study with input from RC and VC. JC2 (Joyce Chilekwa) contributed to the development of data collection tools and collected data during intervention implementation. KG, JC1 and JC2 oversaw data collection at endline. KG analysed the data with input from JC1. KG drafted the manuscript and all co-authors contributed revisions to the manuscript. KG had final responsibility for the decision to submit for publication.

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Table 1: Process Evaluation Domains, Research Questions and Methods

Evaluation Domain	Research Question(s)	Intervention Component	Data Source	Data Captured	Timing
Fidelity & Dose Delivered	What is delivered during the intervention? How and why does this depart from what was intended with respect to both quality and quantity?	All	Document review & Implementer logs	Creative Agency's perspective on intervention delivery (Report); Information on deviations from planned activities (Intervention Schedule spreadsheet)	4-6 weeks post intervention
			Semi-structured interviews (Creative & Implementation agencies; Coordinating Body)	Reasons for any deviations from planned activities	Midway through intervention
		Radio	Media Monitoring Log	Content and quality of delivery	Throughout intervention
		Women's Forums & Road Shows	Implementer logs & Field observation	Activities conducted and challenges faced (weekly logs); Content and quality of delivery according to an observation checklist	Throughout intervention
			Semi-structured interviews & Focus group (*Komboni Housewives* Implementers)	Successes and challenges of intervention delivery from perspective of the implementers	Midway through intervention & 4-6 weeks post intervention
		ORT Corner Sessions	Implementer logs	Activities conducted, availability of supplies and challenges faced	Throughout intervention
			Field observation	Content and quality of delivery according to an observation checklist	4-6 weeks post intervention
			Semi-structured interviews (NHC Implementers)	Successes and challenges of intervention delivery from perspective of the implementers	Midway through intervention & 4-6 weeks post intervention
Reach	To what degree does the intervention contact the target population in each setting? Which subgroups are reached? What explains the pattern of reach achieved?	All	Household survey	Proportion of sample reporting attendance of each intervention component in each intervention and control cluster	4-6 weeks post intervention
		Women's Forums, ORT Corner Sessions & Road Shows	Implementer logs	Number of individuals from target population attending Forums and ORT Corner Sessions. Number of men, women and children attending Road Shows	Throughout intervention
		Radio	Household survey	Proportion of sample reporting listening to the radio show at least once in each intervention and control cluster	4-6 weeks post intervention
Recruitment	How do recruitment strategies affect the pattern of reach achieved?	All	Semi-structured interviews & focus group (*Komboni Housewives* Implementers)	Recruitment strategies and challenges in each cluster (to enable comparison with the levels of reach achieved in that cluster)	Midway through intervention & 4-6 weeks post intervention
Participant Engagement & Responses	To what extent do intervention recipients actively engage with the intervention and understand and retain key messages?	All	Structured interviews (pairs of recipients)	Comprehension of messages and emotional responses to the intervention	Throughout intervention
			Household survey	Recall and recognition of intervention concept, messages	4-6 weeks post intervention
			Semi-structured interviews & focus groups (recipients)	Retention of key messages and reflections on the intervention	4-6 weeks post intervention
Mediators	How do behavioural determinants change as a result of exposure to the intervention?	All	Household survey	Quantitative capture of indicators relating to hypothesised behavioural determinants	At baseline & 4-6 weeks post intervention
		All	Focus groups (recipients & non-recipients)	Comparison of reactions to gossip in relation to the target behaviours in intervention & control groups	4-6 weeks post intervention
Acceptability	How acceptable was the intervention to recipients and implementers?	ORT Corner Sessions	Semi-structured interviews (clinic staff)	Health Centre perspective on ORT Corner Sessions	4-6 weeks post intervention
		All	Semi-structured interviews & focus group (recipients & implementers)	Acceptability of intervention messages and activities	Throughout intervention & 4-6 weeks post intervention
Context	How do contextual factors (events and influences in the intervention setting and environment) encourage or impede intervention implementation and uptake?	All	Document review & semi-structured interviews (clinic staff)	Data on zinc supply; Information on the (clinic) environment and work load of staff; Data on delivery & receipt in clusters, including features of each site (synthesised from data collected from other sources)	At baseline, throughout intervention & 4-6 weeks post intervention

Table 2: Dose Delivered and Reach for Each Intervention Component and Cluster

		ORT CORNER SESSIONS					WOMEN'S FORUMS				ROAD SHOWS				RADIO		TOTAL REACH
		Dose		Reach			Dose		Reach		Dose	Reach			Dose	Reach	
Site	Clinic Catchment Pop	Total No. Sessions Held	Mean No. Sessions per Day	Total No. Recipients	% Target Pop Attended Corner[1]	% Target Pop Attended Prize Draw[1]	Total No. Forums Held	Mean No. Forums per Day	Total No. Recipients (% from target pop)	% Target Pop Attended[1]	Order of Road Shows	Estimated Total Recipients	% Total Pop Attended[2]	% Target Pop Attended[1]	Total No. Call-in Shows[3]	% Target Pop Heard Radio Show[1]	% Target Pop Attended ≥1 Face-to-Face Event[1]
1.Peri-urban	46766	178	1.41	1339	1.8%	0%	23	1.9	342 (94.4)	3.5%	3rd	1900	9.9%	5.0%	7	48.5%	14.0%
2.Peri-urban	112695	193	1.55	1091	8.3%	3.3%	23	1.9	400 (93.3)	23.3%	1st	1500	28.1%	1.8%	8	36.2%	35.0%
3.Peri-urban	94290	195	1.52	1461	6.7%	6.0%	21	1.9	315 (90.5)	11.7%	4th	1500	8.5%	0	4	18.2%	23.3%
4.Peri-urban	160077	231	1.82	2112	7.0%	0%	22	1.8	443 (80.8)	17.5%	2nd	2000	7.2%	8.9%	6	17.6%	24.6%
5.Semi-rural	26720	158	1.25	1222	5.3%	5.6%	21	1.9	374 (96.5)	9.3%	6th	2200	9.0%	28.6%	5	34.5%	28.0%
6.Semi-rural	31976	174	1.38	1024	18.6%	14.8%	22	1.7	373 (99.5)	28.6%	5th	1600	22.5%	16.0%	6	40.9%	61.4%
7.Rural	13715	137	1.08	678	27.4%	26.4%	12	1.0	230 (98.3)	27.4%	7th	1200	51.2%	38.7%	6	47.8%	66.1%
8.Rural	9955	120	0.95	517	23.1%	13.5%	14	1.0	246 (99.6)	19.2%	8th	1700	139.2%*	42.3%	8	35.3%	61.5%
Total	**496,194**	**1386**	**1.37**	**9444**	**12.3%**	**8.7%**	**158**	**1.64**	**2723 (96.1)**	**17.6%**		**13,600**	**34.5%**	**17.6%**		**34.9%**	**39.3%**

***O**RT Corner sessions (and Prize Draws) were delivered at clinics and recipients originated from throughout the clinic catchment area. Reach of ORT Corner sessions within the target population is therefore lower for ORT Corners than Women's Forums which were delivered within the communities inhabited by the target population. Attendance was not documented at the prize draws. ORT Corners ran Monday to Friday in each site, while forums ran from Monday to Friday and rotated between sites which is reflected in calculation of the number of events held per day.*

[1] Reach estimated using endline survey data from two random samples used to measure intervention outcomes: i) caregivers of children under-five with recent diarrhoea; ii) caregivers of infants under six months-of-age.

[2] Reach estimated using data from a census conducted in the intervention areas during the intervention period. The target population of the road shows was the whole community so reach is reported for the total population.

[3] Radio shows aired three times a week throughout the six-month intervention period. Radio call-in shows required the radio DJ to contact a women's forum and numbers do not therefore reflect total airtime.

** Road show may have attracted individuals from other communities or there may have been an issue with the denominator.*

Table 3: Fidelity of delivery of face-to-face intervention components

	Intended intervention content	Deviations during delivery	Quality of delivered intervention
WOMEN'S FORUMS - *Delivered by Komboni Housewife actors in a host household in the community*			
Technology	Included Films shown on large screens	Films not available until partway through the implementation period	Films needed to be shown on tablets as there was too much glare from the sun to view screens
General	Behaviours targeted using: 1) skits to associate practice of the target behaviour with social approval; 2) discussion with question and answer sessions; 3) emotionally engaging demonstrations; and 4) short films featuring the Komboni Housewives. Activities supported by banners, certificates, stickers, a branded bus and prizes (hats, T-shirts).	Implementers deliberately modified skits and discussions to incorporate stories from the community with a view to increasing relevance for target population	Some forums were held in busy thoroughfares which distracted the implementers and participants alike
Exclusive breastfeeding	Skits, discussion, emotional 'baby tummy' demonstration and short film	Skits and discussions modified to include more information on HIV and other issues the implementers felt increased the relevance of the intervention.	Intervention content delivered in an engaging way, reasonable knowledge on target behaviours exhibited. Quality of demonstrations generally very good.
Handwashing with soap	Skits, discussion, emotional 'shit & shake' demonstration and short film	Observed demonstrations of handwashing technique were added in to handwashing skits	
ORS	Skits, discussion, skill-based demonstration and audience participation on ORS preparation and short film	No substantial changes	
Zinc	Skits, discussion and short film	No substantial changes	
ORT CORNER SESSIONS - *Delivered by pairs of Neighbourhood Health Committee volunteers (NHCs) at clinics*			
Technology	N/A	N/A	N/A
General	Behaviours (except handwashing) targeted using: 1) discussion with Q and A sessions; and 2) emotionally engaging demonstrations. Activities supported by banners, certificates, stickers and prizes (measuring containers for ORS preparation). Entry into prize draw.	Implementers strayed from the script to add in other educational messages that they felt it was important to share with the target population and did not always link to the prize draw or Komboni Housewives' events.	Quality compromised in sites with busy, noisy settings
Exclusive breastfeeding	Discussion & emotional 'baby tummy' demonstration with audience participation	Implementers added general information on child nutrition and feeding	Delivery varied from cluster to cluster due to the different implementers at each site. Some were more organised and engaging than others, but demonstrations sometimes lacked enthusiasm.
Handwashing with soap	No handwashing messaging included due to desire to keep sessions brief	Implementers promoted handwashing before preparing ORS and before breastfeeding	
ORS	Discussion & skill-based demonstration with audience participation	NHCs did not always encourage a volunteer to prepare ORS as intended	
Zinc	Raise awareness and demand for zinc through discussion about the role of zinc (together with ORS) in diarrhoea treatment	Generally good. Sometimes the explanation about the dosage was missed and little time was spent discussing zinc even when mothers were confused.	
ROAD SHOWS - *Delivered by Komboni Housewife actors and MCs at large events held in the community*			
Technology	Included Films shown on large screens	Delay in production of films caused road shows to be delivered towards the end of the intervention period rather than at the start to raise awareness	Films could not be seen and heard from all locations in large road shows
General	Similar content to the forums. Faciliated by MCs and included a performance from a famous Zambian musician.	Change in the timing of the road shows meant the celebrity musician was unable to attend two events	First road show was too long (5 hours), others were shortened to 3 hours to prevent attrition and improved greatly in quality. Lack of shade was an issue in some sites. The crowd came to hear the musician and on occasions when he had to perform early this affected attention and attendance
Exclusive breastfeeding		No issues	
Handwashing with soap		Handwashing messaging forgotten at some events until reminded. Instruction on proper technique added in.	
ORS		No issues	
Zinc		Incorrect messages given by the MCs in the first road show which had to be corrected	

Figure 1. Images from the *Komboni Housewives* Intervention

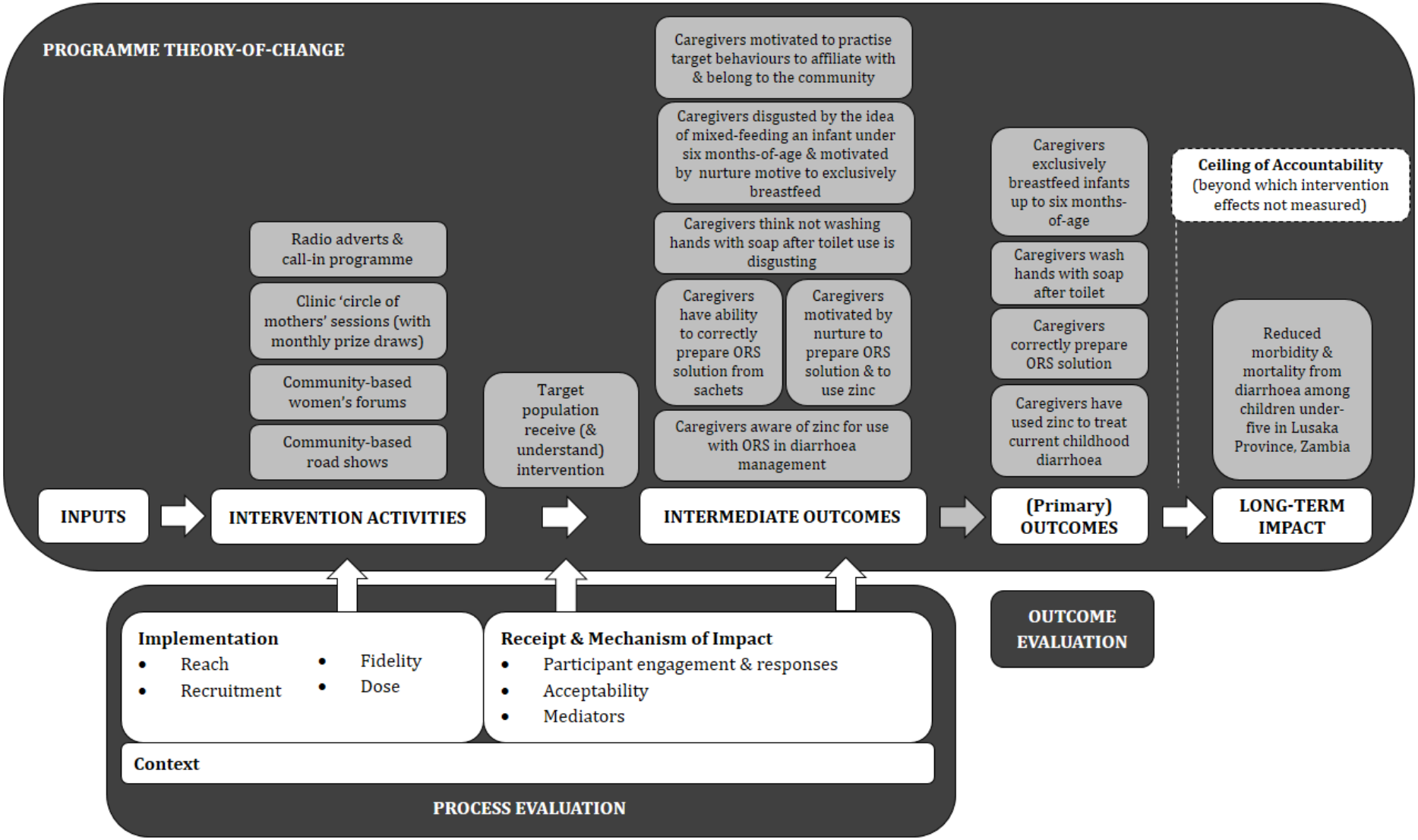

Figure 2. Process evaluation framework

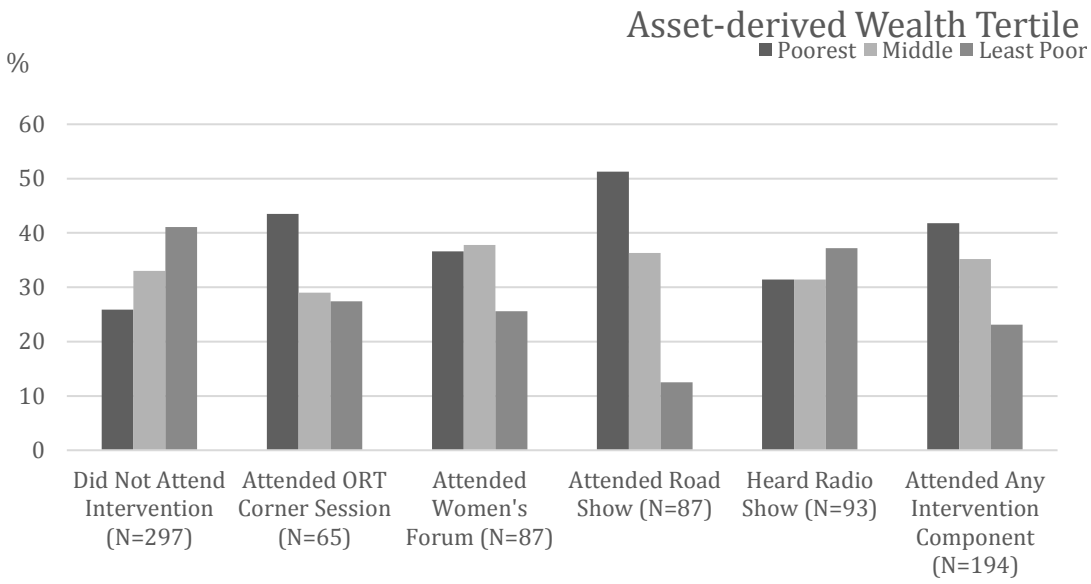

Figure 3. Relationship between wealth tertile and reported intervention attendance

Figure 4. Word Cloud of Intervention Recipients' Reactions towards the Emotional Demonstration to Promote Exclusive Breastfeeding. *Greater prominence is given to words and phrases that were used more frequently.*

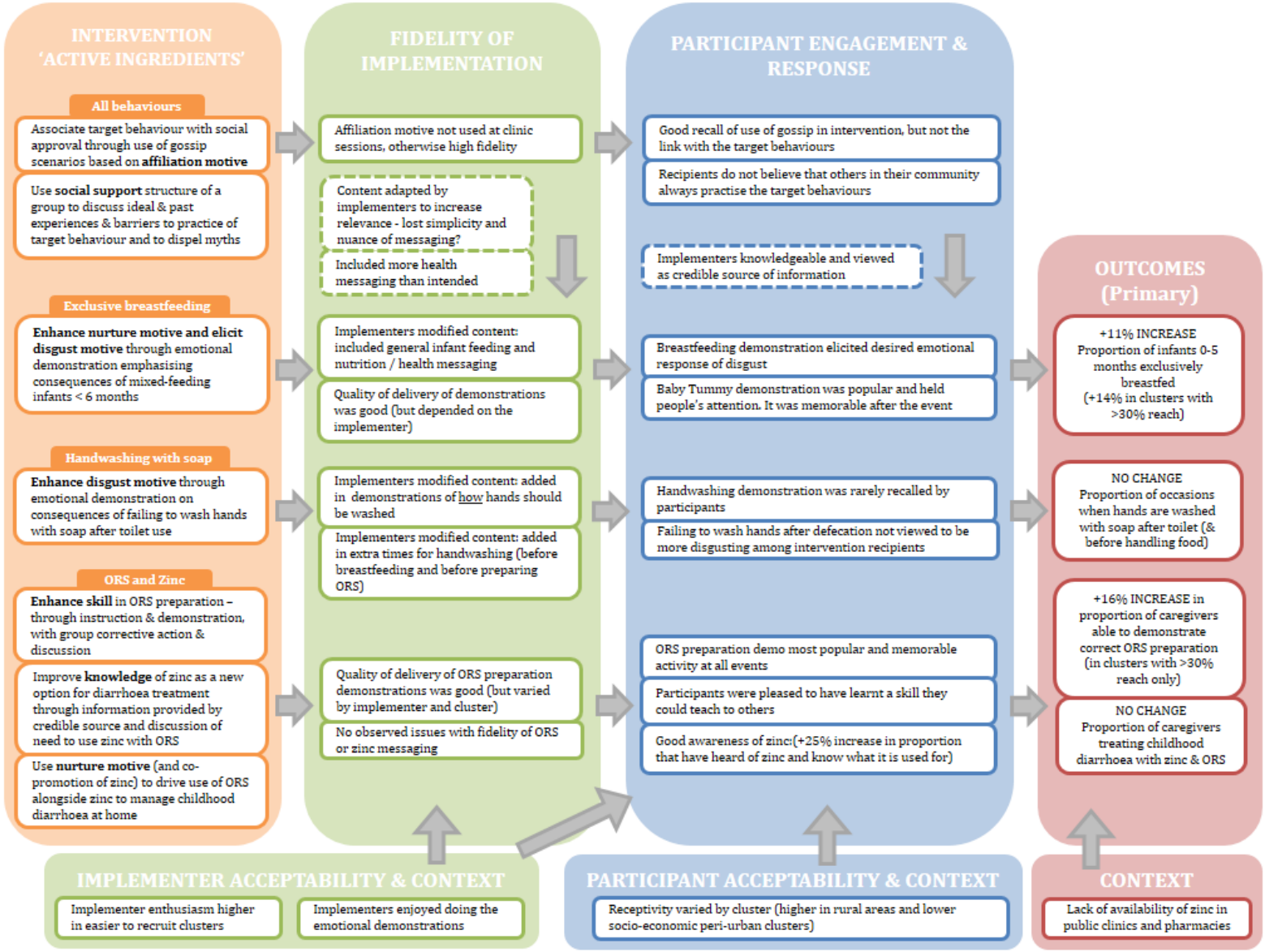

Figure 5. Proposed mechanism by which the intervention and its implementation influenced behavioural determinants and behavioural outcomes

8.4 Additional results from the process evaluation

The process evaluation involved synthesis of a large amount of data. It is not possible to do justice to the richness of these data in an academic article. In this section I describe and discuss additional findings concerning contextual moderators and quantitative data on mediators that are not already included in Research Paper 4. These areas have been singled out for further examination because the information they provide guides the interpretation of intervention outcomes and decisions about the future of an intervention. These elements of investigation are also under-represented in most reports of process data.

8.4.1 Contextual moderators

Contextual factors can affect intervention effectiveness because they shape what is implemented in an intervention. They also play a role in determining how individuals interact with the delivered content. Studying context is thus important in the interpretation of intervention effects. Understanding the conditions under which an intervention works or fails (Pawson and Tilley, 1997) helps answer questions about the potential for success or failure in other settings (Wells et al., 2012). However, as the intervention and the context in which it is delivered are so entwined, assessing context in a complex intervention has been described as a *"bewildering task"* (Moore et al., 2015).

Table 8-1 summarises the characteristics of each intervention cluster and clinic and reports qualitatively how these contextual factors affected intervention implementation.

Table 8-1. Characteristics of intervention sites and the influence on implementation

Cluster	Characteristics	Influence of Context on Forums	Clinic Setting	Influence of Clinic Context on ORT Corner Sessions
1 (Peri-urban) **Reach:** Forums 3.5% ORT Corner Sessions 1.8%	Higher socio-economic status; block structure rather than sprawling settlement. Homes were often walled and sometimes gated.	 Recruitment was challenging due to the nature of the housing and the slightly higher status of the inhabitants: women were often working and busy. Finding host households for a forum and recruiting women took time.	**Clinic type:** Health Centre **Catchment pop:** 46, 766 **Staffing:** 3 Clinical Officers 3 Registered Nurses 8 Enrolled Nurses 1 Registered Midwife 3 Enrolled Midwives 2 Environmental Health Technicians (EHTs)	 Sessions are held outside so no protection from the elements. Decorating the corner was difficult due to the location. *"There was no tent for us to sit in hence we were forced to sit under the sun."* *"Our clinic is near a bar so sometimes it was hard for them to pay attention."*
2 (Peri-urban) **Reach:** Forums 23.3% ORT Corner Sessions 8.3%	Densely-populated, limited private space in living environment. Low income, sprawling settlement.	 Mobilisation of women was easy and the implementers enjoyed working there. The crowded setting meant non-target mothers would also sit in on the sessions. *"We used to have crowded forums for [Cluster 2 and 4], but the attention was there. We never struggled for anything."*	**Clinic type:** Referral Centre **Catchment pop:** 112, 695 **Staffing:** 2 Doctors 10 Clinical Officers 17 Registered Nurses 24 Enrolled Nurses 2 Registered Midwives 10 Enrolled Midwives 3 Dentists 5 EHTs 3 Lab Technicians 1 Physiotherapist 2 Nutritionists	 The location of the ORT corner sessions was good. They had plenty of space. However, the venue was quite far from other clinic activities. It was difficult to coordinate the sessions with the purpose for clinic attendance until clinic staff were brought on board. One implementer had to be replaced.

Cluster	Characteristics	Influence of Context on Forums	Clinic Setting	Influence of Clinic Context on ORT Corner Sessions
3 (Peri-urban) **Reach:** Forums 11.7% ORT Corner Sessions 6.7%	Similar to cluster 1, housing is less crowded than clusters 2 and 4 and cluster inhabitants are slightly more affluent. Housing can be walled.	 *"It was such a challenge to do the whole programme and finish it on time [in Cluster 1], in [Cluster 3] too. Basically it was the location; they have no time to waste. Even when it was time to go to [Cluster 1 and 3] we felt it [was difficult]".*	**Clinic type:** Out-patient department & ART Health Centre **Catchment pop:** 94, 290 **Staffing:** 4 Clinical Officers 3 Registered Nurses 6 Enrolled Nurses 3 Enrolled Midwives 1 Dentist 2 EHTs 2 Pharmacists 75 (??) Lab Technicians	 The sessions were held in the actual ORT corner. The area is quite small and only separated from the Out-patient department by a board. Everyone passes the corner so it was very visible.
4 (Peri-urban) **Reach:** Forums 17.5% ORT Corner Sessions 7.0%	The cluster is very similar to cluster 2. It is densely-populated and there is limited space for privacy.	 As for cluster 2: mobilisation of women was easy and the implementers enjoyed working there. The crowded setting meant non-target mothers would also sit in on the sessions.	**Clinic type:** Health Centre **Catchment pop:** 160, 077 **Staffing:** 1 Doctor 9 Clinical Officers 4 Registered Nurses 7 Enrolled Nurses 5 Registered Midwives 7 Enrolled Midwives 1 Dentist 1 EHT 3 Pharmacists 2 Lab Technicians 1 Physiotherapist 1 Nutritionist	 The sessions were held in the actual ORT corner. This location is in the middle of the waiting room which means the sessions drew a crowd but there was a lot of noise and distraction: *"The space was just OK, only that sometimes when participants came in big numbers some would stand."*

Cluster	Characteristics	Influence of Context on Forums	Clinic Setting	Influence of Clinic Context on ORT Corner Sessions
5 (Semi-rural) **Reach:** Forums 9.3% ORT Corner Sessions 5.3%	Although this cluster is in a rural area, people live closely together in a settlement that is similar to clusters 2 and 4, but somewhat more rural.	 People live close together and the population was very receptive. *"Recruiting the women wasn't all that difficult... they would line up. Each time we would go we would find many people"*	**Clinic type:** Health Centre **Catchment pop:** 26,720 **Staffing:** Unknown (survey missing)	 The actual ORT corner was too small to hold the sessions in, so they were held in a small room in a separate building from the clinic. However, only fit 4 mothers could fit into this site, so another room was used whenever possible. The sessions were thus not very visible.
6 (semi-rural) **Reach:** Forums 28.6% ORT Corner Sessions 18.6%	Similar to cluster 5. Although this is a rural area, the people here are factory workers and live in a neighbouring settlement. The conditions are not as poor as peri-urban slums, but the density of housing is high.	 As described for cluster 5, people live close together and the population was very receptive. *"[The houses] are so close, so whenever you find a venue you don't struggle [to recruit mothers], you just reach there and do it. [One woman] started following us wherever we were and started organising women."*	**Clinic type:** Health Centre **Catchment pop:** 31,976 **Staffing:** 2 Clinical Officers 4 Registered Nurses (1 is part-time) 5 Enrolled Nurses 1 Registered Midwife (part-time) 6 Enrolled Midwives 2 EHTs 1 Pharmacist 1 Lab Technician	 The site was quite well-located, there was plenty of space and the corner was visible to people visiting the clinic. They were planning to paint the room, so it couldn't be decorated and it was sometimes necessary to change the location. *"The room that we were using was the room that TB drugs were being given so we would go to M.C.H. The shifting was inconvenient sometimes."*

Cluster	Characteristics	Influence of Context on Forums	Clinic Setting	Influence of Clinic Context on ORT Corner Sessions
7 (rural) **Reach:** Forums 27.4% ORT Corner Sessions 27.4%	Rural, remote location with subsistence farming. Households are quite scattered.	 There was plenty of space for the forums to be held in quiet locations, but it took time to assemble women even though a local person helped with the recruitment. Only one forum could be held per day.	**Clinic type:** Rural Health Centre **Catchment pop:** 13,715 **Staffing:** 2 Enrolled Nurses 1 EHT	 The sessions were held in the site of the old male ward. It was a big room with sufficient space and no disturbances. *"It was well known to everyone whoever comes here at the centre... it accommodates a big number."*
8 (rural) **Reach:** Forums 19.2% ORT Corner Sessions 23.1%	Similar to cluster 7, remote location with scattered households.	 Similar to cluster 7. However, recruitment was more challenging as the implementers had no assistance. *"For [Cluster 8] we didn't have anyone to help us. We would wait for people to come. Most of the times you go there you find that most mothers are in the field and that would delay us, but we were not in a hurry because we only had one forum a day."*	**Clinic type:** Rural Health Centre **Catchment pop:** 9955 **Staffing:** 1 Clinical Officer 2 Enrolled Nurses 1 Enrolled Midwife 1 EHT	 *"People know it well. The location was well-situated because it was in public and at the entry point."*  *" We would experience problems due to people constantly passing and making noise."*

As seen in Table 8-1, the characteristics of individual clusters and clinics affected delivery of the women's forums and ORT corner sessions, respectively. Although the setting did not directly affect fidelity, the differing physical environment and attitude of the recipients in each cluster and event would undoubtedly have affected the quality of the implemented intervention. The suitability of the delivery channels for use in the *Komboni Housewives* intervention is discussed below.

In the words of one *Komboni Housewife* implementer: *"Every forum was different".* The challenges facing forum delivery in rural areas mainly related to the difficult terrain and low population density. These challenges are likely to be similar in other rural settings. It is therefore possible to speculate that delivery of a similar intervention could be made more feasible if more time is spent developing recruitment strategies in rural areas. The remaining peri-urban and semi-rural intervention clusters were more dissimilar. They differed with respect to the density and type of housing, as well as the characteristics of the inhabitants. These factors affected recruitment and, in turn, the reach of forums. Community forums may not be a suitable delivery channel in slightly more affluent areas. Reviewing the type of housing and the socio-economic characteristics of individuals living in a given area may provide an indication of the feasibility of including forums in a delivery strategy. However, achieving high coverage of small community events such as forums in densely-populated areas will always be challenging.

The physical layout of a clinic also affected recruitment. Some ORT corner sessions could be held at the site of the existing ORT corner, thus promoting this under-utilised clinic resource. Other clinics were forced to hold the sessions in a separate building that was often harder to locate. The former sessions were often plagued by noise and other distractions, while the latter made it harder to recruit recipients. However, these challenges would exist in every clinic regardless of the programme. As queues at clinics are often long (observed during the formative research), the decision was made to hold the sessions during this otherwise wasted waiting time. If this element of the intervention were to be scaled up, it may be more appropriate to allow each intervention clinic to determine when sessions should be held, to make the best use of resources and reach the greatest proportion of the target population.

Reflecting on the different characteristics of intervention clusters and clinics enables useful lessons to be drawn about the suitability of the delivery channels.

8.4.2 Mediators

Data on hypothesised mediators – intermediate processes which explain subsequent changes in outcomes (Moore et al., 2015) – were intended to be used in mediation analysis to test the mechanism of change for each target behaviour (MacKinnon et al., 2007). However, as the intervention resulted in limited change in the target behaviours, and no difference between study arms with respect to the tested mediators (see Table 8-2 below), mediation analysis was not performed.

Table 8-2 presents descriptive statistics on the tested mediators of exclusive breastfeeding behaviour, stratified by intervention arm. All data presented are cluster-level means and show the proportion of individuals agreeing with the statement indicated in the table. As intervention exposure was generally quite low, data are reported for a per-protocol population as well as the intention-to-treat population.

Table 8-2. Cluster-level distribution of hypothesised mediators of exclusive breastfeeding by study arm in intention-to-treat and per-protocol population

	Intention-to-treat Population				Per-Protocol Population			
Agreement with statement:	**Control (%)**	**Intervention (%)**	**Difference**	***P*-value**	**Control (%)**	**Intervention (%)**	**Difference**	***P*-value**
I think my neighbours give their babies food & drink before 6 months	28.9	33.7	-4.8%	0.53	28.8	22.9	5.9%	0.53
I think mothers should not give their babies any food or drink before 6 months	36.4	27.9	8.5%	0.16	36.8	32.4	4.4%	0.60
My family members advise me to give my baby food & drink before 6 months	53.7	61.3	-7.6%	0.27	54.3	68.1	-13.8%	0.15
Feeding porridge to my baby at 4 or 5 months would cause neighbours to gossip about me	56.1	49.2	6.9%	0.46	56.7	44.9	11.8%	0.35
I think that only giving breast milk up to 6 months helps me to belong in the community	26.2	21.9	4.3%	0.53	26.3	18.4	7.9%	0.23
If my child is fed on breast milk alone (s)he will not grow as big as a mixed-fed baby	64.6	74.4	-9.8%	0.14	64.2	69.9	-5.7%	0.39
My neighbours advise me to give my baby food & drink before 6 months	51.3	59.7	-8.4%	0.18	51.2	55.1	-3.9%	0.56
I plan to give my baby only breast milk until he/she is 6 months old	44.3	31.7	12.6%	0.20	44.6	37.7	6.9%	0.49
It is not possible for me to give my child only breast milk up to 6 months because I have to go for work / business	59.9	67.6	-7.7%	0.34	60.1	65.3	-5.2%	0.54
It is disgusting for me to give my baby food or drink before 6 months	57	51.3	5.7%	0.49	57.6	50.6	7.0%	0.42

Intervention allocation was not associated with any significant differences in hypothesised mediators of the target behaviours post-intervention. As discussed in Research Paper 3, it is difficult to understand why mediators did not change, but reported exclusive breastfeeding practice did. Further reflections on why the intervention produced its measured effects follow in the discussion in Chapter 9.

8.5 Chapter references

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PART IV

Discussion and implications

Chapter 9: Discussion and implications

9.1 Overview of chapter

This final chapter reflects on the research conducted in this thesis and outlines the key implications of the study findings for future research and practice. Limitations of the research are also reported. The thesis concludes with some brief closing remarks.

9.2 Research findings and methodology

The research reported in this thesis aimed to develop and rigorously evaluate whether and how a novel, theory-based, multiple behaviour change intervention could improve caregiver practice of four behaviours associated with diarrhoea prevention and management. In order to achieve this aim, I undertook formative research to inform the design of an intervention using the Behaviour Centred Design approach (Objective 1). I evaluated the impact of the resulting intervention through a cluster-randomised trial (Objective 2). Alongside this trial, I led a mixed-methods process evaluation to study how the intervention produced the measured behavioural outcomes (Objective 3).

The overarching goal of this research was to contribute to improved intervention design and evaluation in the field of diarrhoea control. In addition to testing the effectiveness of the intervention, the study provided a vehicle for exploring more general theoretical and methodological issues. The main study findings are discussed with respect to: i) the utility of conducting formative research based on the Evo-Eco theory; ii) the appropriateness of the intervention design; and iii) the utility of basing the process evaluation on the intervention's theory of change. This section seeks to complement rather than repeat information included in Research Papers 1-3.

9.2.1 Utility of theory-based formative research

The formative research was based on the Evo-Eco theory of behaviour (Aunger and Curtis, 2014). The research was grounded in theory on the premise that the resulting intervention would be more likely to be effective. The formative research documented the ways in which current practice of the four target behaviours among caregivers of children under-five in Lusaka Province was suboptimal. As well as confirming the need for intervention, the research enabled us to determine precise and locally-relevant behaviour change tasks for the intervention.

Prior to this study, information on the practice of these behaviours elsewhere in Zambia was largely restricted to behaviour reported by respondents in Demographic and Health surveys (Central Statistical Office [Zambia] et al., 2014). A number of reports of cross-sectional or qualitative studies on infant feeding were available, but they had predominantly been conducted in populations of HIV-positive mothers and had not documented actual practices (Omari et al., 2003, Fjeld et al., 2008, Chisenga et al., 2011, Katepa-Bwalya et al., 2015). We used a range of formative research methods, mostly focussed on actual behaviour rather than self-report, as suggested by the Behaviour Centred Design approach to intervention design (Aunger and Curtis, 2016). Video observation over a four-hour period and video recording of ORS preparation were particularly valuable for their role in generating rich data on actual practices and the contextual factors influencing these practices. Directly observing behaviour to inform intervention development is not unique to our study or field (Higgins et al., 1996, Curtis et al., 1997, Biran et al., 2005, Young et al., 2006, Greenland et al., 2013), but it remains uncommon. Observation enabled us to gain a far more detailed and accurate picture of local practices than we could have obtained through other means.

The formative research also generated insights regarding a number of potentially modifiable psychological and environmental factors influencing the target behaviours. Although other formative research studies may also explore factors facilitating and inhibiting practice of the target behaviours, these questions are usually addressed through interviews (Winch and Fitzgerald, 2004), or through 'Doer/Non-Doer' case-control studies and barrier analysis (Kittle, 2013). Case-control evidence about the characteristics of people who perform the desired behaviours provides information on the target audience, but the results are of

limited use in changing behaviour. Socio-demographic factors cannot be easily changed and cognitive influences on behaviour (such as knowledge) that are identified may not be as important as other factors that are not assessed. Barrier analysis offers a long list of barriers that an intervention should seek to overcome. However, identified barriers are often reported by 'doers' as well as 'non-doers' (Curtis et al., 2009), so this does not necessarily generate information to inform intervention development. Structuring the investigation of behavioural determinants around the Evo-Eco theoretical framework (Aunger and Curtis, 2014) offered a systematic way of investigating a wide range of determinants of behaviour. However, it was not possible to ascertain the relationships between these determinants, or discover which, if any, factors were universally important precursors of behaviour. Consequently, the process of using insights about behavioural determinants from formative research findings in the design of a theory-based intervention required creative thinking in a style that is more common in marketing (Zaltman, 2003).

A related point concerns the difficulty of studying determinants that cannot be (correctly) identified, rationalised or reported. The study of motives using techniques such as vignettes (Finch, 1987) was central to the formative research, as motives are central to the Behaviour Centred Design approach (Aunger and Curtis, 2016). However, investigating motives relies on respondents being able to feel and articulate their own motivations, and there is not always a good one-to-one correlation between a motive and its felt experience. For example, the motive *affiliation* can be manifested through feelings of sympathy, anxiety, loneliness, panic, grief, gratitude, or elevation (Aunger and Curtis, 2013). The inability to accurately measure subconscious motives and explore how they determine behaviour remains a limitation of the approach. Nevertheless, formative research guided by behaviour theory arguably improves the breadth of information that can be gathered on what needs to change and how this change could be accomplished through an intervention.

9.2.2 Appropriateness of intervention design

The *Komboni Housewives* intervention was designed to change multiple behaviours simultaneously using multiple intervention components delivered through different channels. The evaluation found that the intervention was associated with a small improvement in the reported practice of exclusive breastfeeding among infants 0-5 months-of-age, but no significant improvement in the other target behaviours, except in areas of higher coverage.

There are a number of possible reasons why the intervention's effects were less than expected. The evidence supporting each main hypothesis is reviewed in turn.

1. *Implementation theory*

The intervention's theory of change comprised both implementation theory (what the intervention planned to deliver and how) and programme theory (how the delivered intervention was hypothesised to bring about change). The intervention achieved low reach, but coverage was particularly poor in peri-urban slums. Considerable time was spent developing, piloting and revising the intervention *content* to ensure that it was based on theory and was appropriate for delivery in both peri-urban and rural settings. However, similar energy was not devoted to the development and tailoring of the *delivery channels* and *recruitment strategies*. As a result, the intervention was labour-intensive to deliver in rural areas and did not adequately penetrate communities in peri-urban slums. When an intervention achieves low reach, even if individual intervention components are effective, it is not possible to change behaviour at scale (Glasgow et al., 1999). The delivery strategy was therefore an important contributor to the [lack of] measured intervention effects.

Effectiveness studies of community interventions often fail to reach the target population (Schooler et al., 1997, Merzel and D'Afflitti, 2003). Do we improve coverage by developing innovative delivery strategies, or do we just need to use existing channels more effectively? Improvements could undoubtedly be made to the way that delivery channels are used and combined. Mass media and large events like road shows are useful platforms for raising awareness and generating community buy-in. However, as we discovered, to fulfil their purposes, they need to be delivered *before* more intensive work begins in the community. It may be

possible to achieve high(er) coverage of subsequent, interpersonal intervention components, such as the popular women's forums, by increasing the number of implementers and by marking out a clear implementation 'zone' for each implementer. As can be seen in Figure 9-1, although the forums were spread out within each community, the number of forums held was insufficient to cover the whole target population in crowded peri-urban settings. The intervention needed to be delivered in all eight trial locations, but could have been delivered more intensively in a more limited area. Achieving high coverage of an intervention in both sparsely-populated rural areas and densely-populate peri-urban slums is costly for different reasons. It would be relevant to model the cost-effectiveness of a number of different delivery strategies during the intervention design phase. Nevertheless, if resources are not available to deliver an intervention as intended, it is wiser either to develop more realistic coverage targets, or to adopt a less resource-intensive evaluation design.

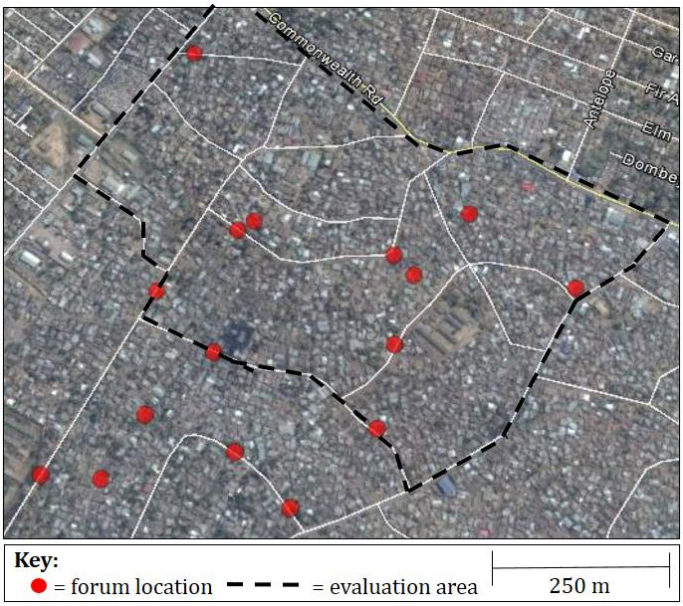

Figure 9-1. Location of women's forums in a peri-urban intervention area

2. *Number and nature of target behaviours*

In addition to targeting multiple behaviours, each behaviour consisted of a number of behaviour change tasks. For example, three distinct messages were actually communicated within the messaging on ORS preparation: i) use ORS as soon as a child gets diarrhoea; ii) prepare this ORS solution correctly; and iii) give ORS for the duration of the diarrhoeal episode. As well as attempting to change too many

aspects of each behaviour, the behaviour change *goals* may also have been too ambitious (Fishbein, 1996). Behaviour change was assessed based on full compliance with recommended practices, but it may have been wiser to focus on eliminating the practices that posed the greatest threat to behavioural compliance. For example, we could have focussed on encouraging caregivers to avoid giving their babies drinks such as *Maheu,* rather than saying *"breastfeed exclusively for six-months".* This may have shifted some mothers from predominant breastfeeding to exclusive breastfeeding, and may have also resulted in a greater improvement in predominant breastfeeding than we observed. It is not possible to determine whether the intervention would have been more effective if it had targeted single behaviours, or had targeted each behaviour in sequence, as opposed to simultaneously. However, if we had specified fewer, simpler behaviour change tasks, it is likely that this would have made it easier to communicate the intervention with high fidelity. Recipients may have also been more likely to retain and act upon the intervention messages.

3. *Use of the 'affiliation' motive*

As everyone tends to follow what other people do, if a health behaviour is not practised very frequently, then the social norm keeps the behaviour at low levels, termed 'interdependence of expectation' (Bicchieri, 2014). Norms can be positively enforced by esteem and acceptance (e.g. *affiliation*), or negatively enforced by disesteem and rejection (Brennan and Pettit, 2004). Use of the *affiliation* motive was central to the intervention. The Behaviour Centred Design approach suggests that behaviour change will occur if an initial stimulus is surprising and causes the recipient to revalue the target behaviour (so that it is preferentially selected next time the behaviour occurs) (Aunger and Curtis, 2016). We hypothesised that the intervention would elicit the *affiliation* motive and that this would cause the target population to believe that practice of the target behaviours would lead to social approval. It appeared that the intervention was surprising, as participants engaged with the novel intervention components, and liked and remembered the *Komboni Housewife* characters. However, following the intervention, people did not believe that other people practised the target behaviours, or that practising the target behaviours would lead to social approval: i.e. neither the descriptive norms (what is commonly done), nor the injunctive norms (what is commonly approved of and

ought to be done) (Cialdini et al., 1990, Cialdini et al., 1991), were measurably altered by the intervention.

We cannot be sure that an intervention based on *affiliation* would not have been more impactful if it had been delivered with greater intensity to a greater proportion of the target population. Nevertheless, these findings demand reflection on the design of interventions seeking to change norms. Cialdini and colleagues have demonstrated empirically that norms only influence behaviour if they are *salient* for the individual at the time that the behaviour takes place (Cialdini et al., 1990, Reno et al., 1993, Kallgren et al., 2000). However, community interventions tend not to take place in the same setting as the behaviours they seek to modify, which makes it harder for messages delivered in an intervention to be recalled at the time that a behaviour is enacted (Kallgren et al., 2000). Adding social value to a behaviour is a reasonable approach to take to try to overcome the problem of transfer of effects from an exposure setting to the target behaviour setting. It may also be useful to review how norms-based HIV programmes using opinion leaders and community peers have succeeded in changing norms (Janz et al., 1996, Kelly, 1999).

4. *Structural barriers*

Even if social norms had changed, it is possible that other barriers would have limited uptake of the target behaviours. Langford and Brick report that uptake of a norms-based handwashing intervention in slums in Nepal was prohibited by a number of structural barriers (Langford and Panter-Brick, 2013). The nature of the structural barriers experienced by slum residents described in their study is consistent with our general findings: for instance, we noted a lack of handwashing infrastructure and ongoing problems with the zinc supply chain at clinics and pharmacies. This suggests that, even if people had desired to improve their behaviours, the intervention may have had limited impact. The findings underscore the importance of designing interventions that influence (and measure) determinants at multiple levels. For example, we could have sought to address zinc supply bottlenecks and could have intervened to influence the practices of healthcare providers.

All of these factors may have contributed to the measured intervention effects. However, as the intervention reach was low, it is not possible to conclude with certainty whether the underlying theory was flawed as well as the delivery strategy.

9.2.3 Utility of theory of change based process evaluation

The theory of change model for the intervention was useful for thinking through the qualitative and quantitative data that needed to be collected to measure process indicators related to implementation theory (dose delivered, reach, recruitment and fidelity). The framework also helped to ensure that data were collected on key links in the hypothesised pathway to change to assess the programme theory (i.e. participant responses and mediators). However, whilst this research has highlighted the importance of delivering an intervention well, a well-delivered intervention can only change behaviour if the programme theory is sound. Although change mechanisms in the *Komboni Housewives* intervention were explored using mixed methods, the low levels of behaviour change and intervention reach, as well as the difficulties associated with the measurement of some psychological mediators, limited the extent to which the mechanism of change could be elucidated.

We may be able to better determine the crucial points where data on relevant indicators need to be collected if we spend more time developing theories of change and considering which aspects of an intervention are complex (Rogers, 2008). However, it is not possible to predict all possible interactions, tipping points, or pathways to change in a complex intervention. Furthermore, behaviour can influence determinants as well as be influenced by determinants. This means that mediation analysis that tests simple, linear pathways to change (MacKinnon et al., 2007, Imai et al., 2011) will never be able to fully capture how change has been brought about by an intervention. Ultimately, we may also need to be more realistic about what we can learn about the causal mechanisms operating in complex interventions evaluated in randomised controlled trials.

Another observation concerns the analysis and reporting of process evaluations. Journals tend to have a strict word limit, which is quickly met when articles follow

CONSORT standards for the reporting of trials (Campbell et al., 2012). This limits the ability to report the findings of outcome and process evaluations in the same paper. Furthermore, as noted by Moore and colleagues in their detailed discussion on the reporting of process evaluations (Moore et al., 2015), many journals interested in publishing trial findings are not willing to publish the results from a complementary process evaluation. Research Paper 2 was published by *Lancet Global Health* (Greenland et al., 2016), but the Editors did not feel that the process evaluation paper (Research Paper 3) would be of interest to their target audience. Nevertheless, Research Paper 2 was published alongside a commentary critiquing the lack of process data (Winch and Thomas, 2016). I have highlighted the forthcoming process evaluation paper in a recently-published Correspondence Letter responding to this commentary (Greenland, 2017). This experience emphasises the importance of making a process evaluation protocol or findings available before or - if possible - alongside the publication of trial outcomes and providing a clear indication of how the papers fit together.

9.3 Main limitations

This section focusses on the limitations of the two main research studies and supplements the information provided in Research Papers 2 and 3.

9.3.1 Cluster-randomised trial

Evaluating interventions through CRTs poses a number of problems. First, the 'fried-egg' design (Hayes and Moulton, 2009) was applied to restrict sampling within each cluster to reduce the potential for contamination at the cluster periphery. The potential for contamination was a legitimate concern, as people do not always attend the clinic nearest to their home. This approach also provided a way of limiting the sampling area in very large clusters. However, this approach has a downside, as intervention effects were only assessed in the 'yolk', and this yolk was centred around each clinic. Individuals living closer to the clinic may be more exposed to other clinic interventions and community outreach activities than those living further away. As a result, the individuals exposed to the intervention may have been less receptive than the wider population.

Another important design feature that may have affected the interpretation of trial outcomes, concerns the potential exposure of control arm participants to the radio component of the intervention. Only 12% of control arm participants reported having heard intervention messages on the radio. Although these messages were passive, and radio messaging represented only a minor component of the intervention, mass media campaigns can change attitudes and behaviour (Noar, 2006, Wakefield et al., 2010), particularly when they are part of a more comprehensive intervention (Nguyen et al., 2016). It is therefore possible that intervention effects may have been underestimated. To my knowledge, the only way of mitigating this possibility would have been to use a non-randomised design.

Exclusive breastfeeding was the only behaviour assessed solely through self-report and the only behaviour to improve significantly following the intervention. The choice to measure breastfeeding exclusivity through self-report was consciously made *in lieu* of identification of a suitable alternative, and steps were taken to try to increase the sensitivity of this measure (see Chapter 6). Although the potential for reporting bias was discussed in Research Paper 2, it is important to reiterate the issues associated with the validity of using a self-reported outcome measure in an intervention designed to influence norms. We cannot discount the possibility that exposure to the intervention increased social desirability bias - the conscious or unconscious reporting of (in this case) better practices. The intervention may also have increased perceptions of the social sensitivity of breastfeeding behaviour, which is also associated with more socially desirable reporting (King and Bruner, 2000).

Evidence from studies of other sensitive topics confirms that interventions may change self-report norms but not behaviour (DiFranceisco et al., 1998, Kristal et al., 1998, Henning et al., 2005, Taber et al., 2009). The duration of the intervention may not have been sufficiently long to achieve these norms changes given the low intensity of implementation and intervention reach. Uncertainty surrounding the influence of social desirability bias on reported exclusive breastfeeding practices could have been reduced by including questions to assess social desirability bias (Reynolds, 1982). Nevertheless, the process evaluation findings support the internal validity of the outcome measures.

The trial of the *Komboni Housewives* intervention fulfilled many of the recommended elements of a 'realist' trial, such as the study of 'for whom' and 'when' the intervention worked, and the exploration of mechanisms of change (Bonell et al., 2012). However, the two-arm design and lack of power to assess the effects of each intervention component, meant that it was not possible to test different combinations of components or assess how intervention outcomes varied with context. A more determined effort to assess the impact of the intervention in diverse clusters could have generated useful additional information to answer 'what works, for whom and under what conditions'.

9.3.2 Process evaluation

The process evaluation involved the collection of a large amount of data to answer a series of research questions. The methods used had some limitations.

Process evaluation reports in the literature tend to focus heavily (or solely) on describing indicators associated with intervention implementation, in part because it is easier than exploring change mechanisms. The process evaluation in this study collected quantitative and qualitative data on mediators and participant response. There are recognised challenges associated with capturing and using data on intermediary outcomes and other contextual factors (Baranowski et al., 1997, Van Belle et al., 2010, Grant et al., 2013). Quantitative data collected on hypothesised mediators came from survey questions with Likert-type scale responses. During baseline analysis, it was observed that there was very little variability in response to Likert-type scale questions across the five response categories (strongly agree, agree, disagree, strongly disagree, don't know). Enumerators suggested that this was because respondents could not differentiate between the different levels of agreement or disagreement. This issue did not come up during piloting of the survey questions, when we tested questions based on a visual analogue scale (Hasson and Arnetz, 2005) as well as the Likert-type scale questions. Nor did it arise during training, when considerable time was spent ensuring that all questions were clear for both enumerators and participants, regardless of the language of survey administration. The lack of quantitative data on mediating variables limited the ability to assess causal mechanisms.

Fidelity was assessed primarily through field observation. The evaluator could easily use their checklist to assess – albeit subjectively - the quality of intervention delivery, the absence of any intervention materials, or the unconscious omission of any intervention content. However, it was not possible to assess how the presence of the evaluator affected observed fidelity. The female assessor tried to mitigate potential reactivity by not announcing her arrival and by sitting quietly at the back of the group. She reported that the implementers were not always aware of her presence until she approached them at the end of the session. This suggests that reactivity is unlikely to have been an important influence on the measurement of fidelity, although it cannot be entirely discounted.

Despite these limitations, the research reported by this thesis contributes useful learning that can improve the design, evaluation and ultimately the effectiveness of behaviour change interventions to control childhood diarrhoea.

9.4 Recommendations and implications for research and practice

The evaluation of the *Komboni Housewives* intervention highlights some challenges associated with changing multiple caregiver practices and reinforces the need for continued research to support the development and testing of novel behaviour change interventions. This section describes a number of recommendations with implications for research and practice. The implications of the findings for the future of the *Komboni Housewives* intervention are discussed first, followed by some more general recommendations for the design and evaluation of multiple behaviour change interventions.

9.4.1 The future of the *Komboni Housewives* intervention

Even though the *Komboni Housewives* intervention did not significantly improve all of the target behaviours, some aspects of the intervention are worth exploring further in a refined intervention. When the target population was reached, the intervention was associated with small improvements in two behaviours: exclusive breastfeeding and ORS preparation. This implies that altering the delivery strategy, so that it achieves greater penetration in all communities, could have the potential

to improve the effectiveness of the intervention with respect to these two behaviours. The lack of handwashing behaviour change suggests that the intervention needs considerable revision, if it is to improve the effectiveness of handwashing messaging. New content should take account of structural barriers to change, as well as the perceived lack of interest in handwashing interventions in the target population. New intervention content is also needed to deal with structural barriers to change and thereby move caregivers from improved skill in ORS preparation to increased use of ORS (and zinc) in the management of episodes of childhood diarrhoea. The *Komboni Housewives* theme could be kept as a vehicle to unite the target behaviours and increase public recognition of the intervention.

It would be preferable to deliver and evaluate the revised intervention on a smaller scale so that high coverage can be attained and the impact of the intervention on mediators can be better assessed (Keele, 2015). It may be useful to employ alternative experimental designs to the standard cluster-randomised trial that are better equipped for studying mediation (Imai et al., 2011, Imai et al., 2013). It would also be beneficial to assess the comparative (cost-)effectiveness of alternative delivery strategies. This could involve comparing strategies that target single behaviours with those targeting multiple behaviours sequentially or simultaneously.

The *Komboni Housewives* intervention comprised just one component of a comprehensive programme known as the Programme for the Awareness and Elimination of Diarrhoea described in Chapter 1. Aside from caregiver behaviour change, PAED's strategy also involved the introduction of rotavirus vaccination and improved clinical case management of diarrhoea (Bosomprah et al., 2016). PAED was implemented in Lusaka Province as a pilot scheme, the results of which would inform future diarrhoea control activities in Zambia. The government bought into the medical interventions much more than the less-prioritised behaviour change component of PAED. This is not surprising, given the lack of data on effective behaviour change interventions to encourage them. As the government has limited capacity to drive forward behaviour change research or large-scale programmes, there is a risk that effective behaviour change initiatives will not be sought. Advocacy to create higher levels of buy-in within the Government of Zambia will be necessary if the learnings from the *Komboni Housewives*

intervention are to lead to the development and scale-up of more effective behaviour change interventions in Zambia.

9.4.2 General recommendations for intervention design and evaluation

This work is of importance beyond the above-described implications for the future of the *Komboni Housewives* intervention. Here I make recommendations based on some more general implications of the research findings.

1. *Use (video) observation during formative research to maximise the opportunity to learn about behaviour in context.*

Formative research should always be conducted prior to the design of a behaviour change intervention in a new setting. When it is acceptable to the target population, it is useful to conduct (video) observation during the formative evaluation phase to generate rich data on actual behaviour in context. This can help to ensure that formative research findings used to define or refine the behaviour change tasks of an intervention are based on an accurate understanding of the gap between current practices and desired behaviour.

2. *Formative research would benefit from following a theoretical framework such as Evo-Eco theory.*

Use of the Evo-Eco theory of behaviour as a framework for formative research helps to ensure that a broad range of potential determinants of behaviour can be explored. However, the ability to explore motives was limited, and motives are central to the Behaviour Centred Design approach to intervention design (Aunger and Curtis, 2016). Further research is required to develop better tools to both measure sub-conscious motives and study the connections between different motivations and behaviour.

3. *Further guidance on the process of intervention development following the Behaviour Centred Design approach would be beneficial for programme designers.*

Developing an intervention by combining insights from formative research about the target behaviours and target audience with behaviour change theories and past

experience of intervention success - where it exists - is not a straightforward process. A guidance document that outlines the steps involved in intervention development would be beneficial. This document should describe the development of a creative brief and the use of this brief in intervention development. To be of most use, the creative brief should specify a limited number of behaviour change goals and should outline a set of clear, doable behaviour change tasks required to meet these goals. A theory of change for the intervention should be developed at the outset and should be refined as the intervention content evolves. This theory of change model should specify the intervention activities and indicate how these activities will lead to change. Consideration should be given to the context in which the intervention will be implemented and how the intervention will be evaluated during the development of both the implementation theory and the programme theory.

The development of a guidance document would also be valuable for advocacy purposes, to convince funders and policy makers that sufficient time and resources need to be allocated to intervention design. In the case of the *Komboni Housewives* intervention, the intervention was delivered over six months, but it took over one year to progress from formative research to the final intervention package. Formative research and intervention development cost around 18% of the total budget for the intervention.

4. *Achieving high reach and intensity in community interventions is challenging and further work is required to optimise delivery strategies.*

Further work is required to optimise strategies for the delivery of community interventions, so that they are feasible to implement in both peri-urban and rural settings. Such efforts are likely to require the development and use of appropriate measures of 'implementation strength' in process evaluations, in order that the intensity of delivery required to achieve health gains can be assessed (Hargreaves et al., 2016). We may also need to be more realistic about the levels of reach that are achievable in community behaviour change interventions and assess the cost-effectiveness of different delivery models.

5. *Process evaluations can be strengthened by using an intervention's theory of change as a framework for the collection of process data.*

Process evaluations can collect data on a large number of variables and answer a wide range of research questions. It can thus be challenging to know how to begin to design a process evaluation. Using an intervention's theory of change as the basis for this evaluation helps to refine the focus of a process evaluation, and ensures that both implementation theory and programme theory are evaluated (if that is the goal of the evaluation).

9.5 Concluding remarks

This thesis has described the design and evaluation of a multiple behaviour change intervention for diarrhoea control based on the motive of *affiliation.* The intervention did not succeed in changing multiple behaviours simultaneously, but there was some evidence of multiple behaviour change in clusters where higher levels of reach were attained. Although low intervention exposure limits the conclusions that can be drawn about the utility of motives in behaviour change campaigns, the results suggest that motives-based interventions deserve further development, so that potential change mechanisms can be explored. As well as limiting the ability to understand whether the underlying intervention theory is sound, interventions that do not reach the target population cannot expect to have a public health impact. The findings therefore also underscore the importance of adapting delivery strategies to reflect local contextual differences in the topography and population demographics within a programme area. Further work is required to assess the comparative effectiveness of interventions targeting single and multiple behaviours. However, future interventions targeting multiple behaviours should ensure that each behaviour targeted does not also comprise multiple behaviours. Ongoing research is required, if we are to achieve ambitious goals for the delivery of effective behaviour change interventions to control childhood diarrhoea at-scale. The Behaviour Centred Design approach offers a useful structure for navigating the complexities of the development and evaluation of novel interventions.

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APPENDICES

Appendix A: Creative brief

Developing and implementing a scalable behaviour change intervention for diarrhoea prevention and treatment for the under-5s, in low-income rural and peri-urban Lusaka Province.

① STAKEHOLDERS

Project stakeholders are; Centre for Infectious Disease Research in Zambia (CIDRZ), Zambian Ministry of Community Development, Mother and Child Health (MCDMCH), Ministry of Health (MOH), Absolute Return for Kids (ARK). Research, behaviour change, intervention design and evaluation guidance is from the London School of Hygiene & Tropical Medicine (LSHTM).

② BACKGROUND

What are the facts about diarrhoea and behaviour change?

Every year, Zambia's 2.4 million children under five years of age experience over 10 million episodes of diarrhoea; more than 840,000 of these children visit a health facility at least once for diarrhoea, 63,000 will be hospitalised, and at least 15,000 will die. This brief focuses on three behaviours that have been proven to make a real difference to decreasing these distressing statistics:

- Exclusive breastfeeding (EBF) – which means not giving the child other liquids or foods of *any* sort, up until 6 months of age.
- Handwashing with soap (HWWS) at home after using the toilet or cleaning a child's faeces; and before preparing food, eating, or feeding a child (the latter to be determined).
- Timely use of correctly mixed and administered oral rehydration salts (ORS) with Zinc[2] for diarrhoea among the under fives.

For us these behaviours are linked to diarrhoea prevention/reduction, but this connection may not exist among our target population and is not necessary for behaviour change to happen.

Humans have not evolved a specific 'health' motive and communicating about health rarely initiates healthy behaviours. People the world over often may know 'the right' thing to do but still may not do it (think about yourself!) so education and health messaging is not the route we want to go down. We will not talk about death (or saving lives), diarrhoea or disease instead we will be looking at other ways to shift behaviour.

What do we know about these behaviours now?[3]

1. Infant feeding behaviour:

Mothers are able to tell you that women *should* exclusively breastfeed until their baby is 6 months of age, but in reality most EBF for the first month only and then gradually introduce foods (e.g., porridge) and liquids (e.g. Maheu) alongside breast milk after that. This is claimed to be a response to external factors (e.g., having to go to work; wanting to leave child for longer periods, etc.), infant factors (e.g., no longer satisfied with breast

2 Zinc is largely unavailable in Lusaka Province. Ensuring continuity of supply and access will be essential during the pilot but is not the responsibility of the creative agency.

3 In depth research reports on the three individual behaviours are available.

milk; interest in food; cries too much, etc.), or mother factors (e.g., sickness including HIV-positive status, although HIV-positive mothers may also be more likely to EBF to prevent transmission to the child; milk supply felt to be inadequate; wanting a fat baby, etc.). Mothers typically continue partial breastfeeding up until almost two years. HIV-positive mothers are encouraged to EBF until 6 months and then stop breastfeeding completely. As we did not conduct research based on HIV-status we do not know the extent to which this is practiced. Practices are influenced by grandmothers and female neighbours.

2. *Hand cleansing at home:*

Hands are almost never washed with soap, usually just water, in the specific target moments we are interested in. Hands may be washed with soap only when heavily soiled.

There's usually a bucket of water kept outside for laundry or washing dishes that may also be used for HW. Water is almost always available in and around the home. Water is usually obtained from water kiosks, but as payment is required many people also draw water from other (unprotected) water sources such as wells. Water for drinking and cooking is stored in containers inside the home from where it is decanted into buckets and used as needed. Soap (i.e., powder, paste, or bar) often runs out in the course of a day and is kept inside when not in use (i.e., for laundry). The need to do laundry appears to trigger purchase of soap. [See end of document for images of soaps and water containers.]

Some adult and few child hands are rinsed with water, at the threshold of the home on returning from the toilet. After changing a child, mothers/female caregivers may or may not rinse hands with water only. Before eating the main meal in homes, hands are typically wetted from a special bowl, soap is never used. After eating, hands may be rinsed with the same water. People will say they've heard about washing hands after the toilet and most will say that in this moment, if they do it, they use soap.

3. *Diarrhoea Treatment for Under-5s:*

ORS is a known diarrhoea treatment and believed to give the child 'energy'. There is some very low-level awareness that Zinc is a diarrhoea medicine – and all study participants were interested in it (as they seek *medicine* to stop diarrhoea), but it is not commonly available.

At home, when a child gets diarrhoea, varying time passes before one of the following is tried:

- ORS (if left over at home or can be borrowed from neighbour) - frequently sub-optimally prepared (wrong water/powder ratio, mixed with still hot water after boiling as most ORS is prepared with boiled water) and administered (not continuously enough);
- Other left-over medicines;
- Traditional medicines;
- Sugar/salt "homemade" ORS (more common in rural and no longer recommended).

If the family judge the child isn't improving (stops playing, eating and becomes weak) or is getting worse they are taken to the clinic. At the clinic if severely dehydrated they'll be put on an intravenous drip, if not, a prescription for 1-2 ORS sachets will be given. If the child is moderately dehydrated they may be monitored in an "ORS corner" while ORS is given by the mother. If the clinic pharmacy has run out mothers can buy it from the private pharmacy or return the next day. Zinc is sometimes given although supplies are limited and in rural areas 10 tablet courses may be cut in half (so zinc may not always be prescribed if clinic staff know it is not available). *Home:* ORS is then (again sub-optimally) administered at home until the child's energy picks up.

What else do we feel is critical to know?

Life is lived and children are raised across many households: "your neighbour's child is your child" philosophy. Older infants and children move between households sometimes eating elsewhere, being chided by others, etc. Resources are shared, borrowed, returned or not. TV & radio are seen by more than the people that own them. And the mobile number given to you may be a neighbour's. Visiting friends and relatives is part of daily life (it is important to visit when someone is ill), as is sharing information and knowledge. In compounds, houses are mostly rented and one lives largely communally, under the eye of neighbours outside, during daylight hours at least. Tenure is precarious and people move house a lot. When they move to a new neighbourhood, it takes time to learn where things are (market, clinic etc.) Money may be accessed across households through Kalimba 'revolving loans' although these involve strict rules and can be a source of conflict. Older children also tend to take care of toddlers or babies when mothers are doing household chores.

Status matters: having a child brings a woman status. A well-looked after child (i.e., "a healthy child is a fat child") confers status through competency as a mother. Information as social currency brings or maintains status. Clinic-workers have status and some abuse it by granting favours, treating people poorly, or disappearing when the clinic is busy.

Responding to the child - their state, energy levels, requests, their rebuttals, likes and dislikes - is one way mothers explain how they work out how to nurture children. When my child cries after breastfeeding – surely s/he is asking for other foods? When my child's energy returns - surely it's time to stop giving them ORS? When they look better – surely they are better? This can go beyond 'responding' to them to a more visceral connection, "When my child is sick, I am sick".

'Hoarding' even basic household supplies, is not standard practice. Things are bought as needed or when there's money. Borrowing from neighbours, repurposing (e.g., using left-over drugs to treat a sick child), loans and credit fill resource gaps in emergencies. Having stocks at home could be a stress rather than comfort - if you have surplus it is harder to deny a neighbour's request to borrow. Despite not hoarding household supplies, people seem to save medicines (in a sense, hoarding) e.g. even 'free' ORS or zinc tablets are kept and used sparingly so as not to waste them (e.g., a packet of ORS may be only half prepared, leading to errors in concentration).

③ TARGETS FOR BEHAVIOUR CHANGE

We want to reduce diarrhoea among under-fives in peri-urban and rural low-income households in our Lusaka Province pilot areas. This means changing behaviour among the following groups:

	1. EBF	2. HWWS	3. ORS + Zinc
Households	Mothers of babies under 6 months who still EBF	All old enough to feed selves from family pot and go to toilet unassisted Household heads (men & grandmothers)	Mothers of children 1-59 months Household heads (men & grandmothers)
Clinic staff & health workers	Health workers who promote EBF (?)		Health workers, clinicians, pharmacists
Private pharmacies			Owners, dispensers
Shops, soap sellers		Owners	

④ INTERVENTION DESIGN PRINCIPLES:

Our aim is to change behaviour (not to purely educate or give messages). The following are guidelines for overall intervention design which will help us do this while in section ⑤ we share specific tasks within each targeted behaviour.

- We do not need our target audience to know that the connection between our three behaviours is diarrhoea prevention/treatment. However, we imagine it would be useful to have **a way to connect the three behaviours within a program** because it will:
    - Have a multiplier effect where some aspects of the intervention reinforce others;
    - Make the most of our limited resources if we can bundle things together;
    - Make implementation more consistent and coherent for us.

  Our first thoughts are that this could be: **a message** (e.g., 'My mum when I was young did X, Y, Z and now I'm a big shot'); **a vehicle** (e.g., a radio drama, an authoritative yet approachable advisor like Donald Winnicott or aspirational figure like Michael Power!); **a brand** (e.g., Brothers for Life). We will really value your input!

- As a minimum our intervention must not conflict with, but will ideally **reinforce existing public health messages** for our target behaviours and for diarrhoea[4].
- Must **work for rural and peri-urban settings and be scalable** for the rest of Zambia.
- All **implementation must work for low/no-literacy communities**. 'Orality' (thought and verbal expression in non-literate communities) demands emphasis on understanding through observation and imitation, through practice and reflection, through trial and error, through narrative, rhymes, sayings, repetition, signs, etc. Currently, materials in clinics (i.e., posters) and clinic staff's behaviour (i.e., writing instructions for medicine usage) may not acknowledge this. Successful interventions in non-literate communities often have a highly participatory nature e.g., community-led total sanitation.
- People in our target communities are often used to getting things for free. Health workers and promoters can find it hard to engage people if there is no 'give-aways.' But **giving stuff away *can* reduce its perceived value and make an intervention less sustainable**.
- New information (e.g., zinc stops diarrhoea) and ideas (e.g., HW stations during behaviour trials) are social currency and - if 'proven' through personal experience and/or coming from a high-status source (i.e., clinic) – will often be actively shared. We should see **the creation of social currency to help spread messages and behaviours** as part of our remit but be aware that being able to say something does not equal doing something!

⑤ (MEASURABLE) BEHAVIOURAL TASKS

Desired Behaviour	Measurable Behavioural Tasks
1. EBF for first 6 months:	• Disrupt existing societal 'we say we do but we don't' (e.g., Angelina Jolie's double mastectomy created a whole new conversation about breast cancer prevention). • Address 'for the poor' low status image of breastfeeding – e.g., aspirational role models inc. higher-status mothers, clinic workers in community to EBF, etc. • Piggy- back on existing early intervention- points in early month(s) *before* the first mouthfuls of non-breast milk are introduced and include fathers and grandmothers – i.e., clinic after birth, 6 day visit, 6 week visit, etc. • Make EBF feel doable by re-expressing timeframes – e.g. 'every extra day you EBF' vs. 'EBF for 6 months'. • For key 'events' that prompt first non-breastmilk mouthfuls (e.g. **baby keeps crying after breast**, sore nipples, etc.) find easy, sensible solutions successful EBF mums

[4] CIDRZ can advise on the main messages our target population are likely to be exposed to.

	already use. Spread them in memorable, interesting ways to create a sharable social currency among mothers. • NB: We think people don't understand that EBF means *anything* other than breast milk as some liquids and foods given and may not classify as 'food'. • NB: We also know from previous interventions that peer-to-peer support helps but is it scalable.
2. HWWS at home after toilet, or cleaning up a child's faeces, (and before preparing food, eating or feeding a child?):	• Make soap something households don't run out of – e.g., shop keepers promote the things people should always stock at home • Have a designated place for handwashing with soap next to water outside the home (site for people to decide) - e.g., build-a-HWWS station competition in schools or community. • Make washing hands with soap before food and after the toilet good (neighbourly) manners underpinned by disgust - e.g., show a child asking to wash their hands before eating at a neighbour's home and the neighbour saying something positive to another neighbour about that mother. • Storekeepers stock and promote low-fragrance soaps for HWWS as soap smell on hands before eating is not liked – e.g., point-of-sale stickers. • NB. We have some concern that people are unpractised at using soaps for hand washing. We may need to show or model or encourage trial of this as part of what we do.
3. Timely use of correctly mixed and administered ORS & Zinc for under-5s:	*Clinics:* • Commoditise prescribing practices: 1. Consistently recommend ORS + Zinc as the best *first* treatment for infants' diarrhoea after 3 loose stools. 2. Give enough ORS *and* Zinc for whole episode; 3. Give correct sized tablets for child based on age; 4. Provide physical means for correct ORS dilution (e.g. Kit Yamoy or plastic bag to measure water); 5. Mothers give child first zinc tablet at clinic under supervision (by whom tbd) *6.* Key (missing) behaviours around Zinc + ORS shown and communicated to mothers: correct ORS dilution with drinking water; ORS given continually until diarrhoea stops; Zinc for ten days. *Private pharmacies and other health-workers:* • Consistently recommend ORS + Zinc as the best *first* treatment for infants' diarrhoea after 3 loose stools. *Households:* • Establish practice of *always* having (min 2x full packets) ORS at home – e.g. given out at first visits to clinic (e.g. during 6 week BCG vaccination?) in special hanging bag, health workers do spot-checks with prizes • Make third loose stool call to action to give ORS now and get to the clinic asap for zinc by tapping into women's desire to respond to their child's needs – e.g., 'one thing your child *can't* tell you…' • Key (missing) behaviours around Zinc + ORS practiced: ORS diluted to right volume with potable water (which if boiled must be cooled); ORS given continually until diarrhoea stops; Zinc once a day for10 days – e.g. Kit Yamoy[5] + shown mini video drama of what to do at clinic on mobile phone. • ORS + Zinc becomes what people ask for and recommend to others as the best ***first*** treatment for infants' diarrhoea after 3 loose stools – e.g. one pack communicates about the other.

[5] http://www.grandchallenges.ca/grantee-stars/0144-01/

⑥ AGENCY DELIVERABLES & REQUIREMENTS: The core agency outputs will be:

- Signed off strategy underpinning intervention design – this will specifically help us understand how to manage doing work on three behaviours in communities within the pilot program.
- Signed off overall intervention design.
- Channel/touch-point strategy for execution in both rural and peri-urban locations in Lusaka;
- Development of all materials and interactions associated with this for pilot.

⑦ TIMING & TEAM:

The intervention development process will be led by Jenala Chipungu (CIDRZ) and Katie Greenland (LSHTM). The process and timings and outputs at each stage will be agreed with the agency – and need to fit with baseline measurement, but include the following steps:

Timing	Activity	People
June 7th	Email brief to agency	
June 10th	Face-to-Face Briefing	(Val) Katie, Jenala, Zumbe
June 12th	Present to stakeholders	
June	Agency community immersions & insight hunting through FR materials	
June 14th	Sign off the brief	
July	1st agency response to brief.	
July	1st feedback from client & agree revisions	
July	2nd agency response to brief	
August	2nd feedback from client & agree revisions	
August	Final response to brief	
August	Sign off by client and implementation plan agreed	
August	Pre-testing of materials	
September	Implementation training development	
September-October	Baseline	
October-November	Roll Out	

Soaps and water containers typically found in homes

Appendix B: Household surveys used at endline in the cluster-randomised trial

UNDER-FIVE DIARRHOEA SURVEY

Interview with Female Primary Caregiver

SOCIO-DEMOGRAPHICS Loc ID | FW ID | HH ID

1 How many individuals, including yourself, live in this household, (by household I mean persons who are normally resident and eat together) ? ☐☐

2 How many adult women (18 and over), including yourself, live in this household? ☐☐

3 How many adult men (18 and over), live in this household? ☐☐

4 How many children aged 5 - 17 years live in this household? ☐☐

5 How many children younger than 5 years live in this household? ☐☐

6 How old are you? ☐☐ years ☐ Don't know (tick) **Date of Birth (if known):** ☐☐ Day ☐☐ Month ☐☐ Year

7 What is your marital status? Tick one only

Married/living together	☐ 1	Widowed	☐ 3
Divorced/separated	☐ 2	Unmarried	☐ 4

8 What is your highest level of formal education? Tick one only

Never attended school	☐ 1	Completed secondary school	☐ 5
Attended some primary school	☐ 2	College / vocational training	☐ 6
Completed primary school	☐ 3	University	☐ 7
Attended some secondary	☐ 4	Other	☐ 8

9 DO NOT ASK, VERIFY WITH CONSENT: Is participant literate? No ☐ 1 Yes ☐ 2

10 Do you currently under-take any paid work? This includes any piece-work done

Yes, full time	☐ 1
Yes, part-time	☐ 2
No	☐ 3

11 Which option best describes your current occupation? Tick one only

Salary	☐ 1
Informal work (e.g. piece work)	☐ 2
Presently unemployed / homemaker	☐ 3
Student	☐ 4
Other	☐ 5

12 How much does your family spend on groceries each <u>week</u>?

_____ Kwacha Don't know ☐ 88 Refuse ☐ 99

13 How long have you been living at your current address? ☐☐ Years ☐☐ Months Whole life ☐ (TICK)

Enter years, or months if less than one year, or tick 'whole life'

14 Which tribe do you belong to?

Bemba	☐ 1	Luvale	☐ 6
Lozi	☐ 2	Kaonde	☐ 7
Tonga	☐ 3	Chewa	☐ 8
Soli	☐ 4	Nsenga	☐ 9
Ngoni	☐ 5	Other	☐ 10

15 Does your household or a household member own or have any of the following (in working order)?

Tick all that apply.

	No	Yes		No	Yes
The house you live in			Electricity / Solar		
Land for farming			Mobile telephone (standard)		
Animals (non domestic)			Mobile telephone (smart phone)		
A car			A refrigerator		
A motorbike			A freezer		
A bicycle			A toilet		
Radio			A water tap that works inside the house		
Television					

16 What type of fuel does your household mainly use for cooking?

Tick one only, if they use more than one type ask which is most common

Charcoal		1
Wood		2
Electricity		3
Other		4

17 How many rooms does the house have? ☐☐ (enter number)

Only record the rooms the household use (i.e. If house with 7 rooms but they have 1record 1)

18 What type of house is it?

Free standing		1
Flat		2 --------> ☐ (enter number of houses connected to each other)
High rise		3

19 DON'T ASK, OBSERVE: What is the main material of the FLOOR of the house?

Tick one only

Mud		1
Cement		2
Tiled		3
Other		4

20 DON'T ASK, OBSERVE: What is the main material of the WALLS of the house?

Tick one only

Mud		1	Cement		4
Bamboo		2	Brick		5
Wood		3	Other		6

21 DON't ASK, OBSERVE: What is the main material of the ROOF of the house?

Tick one only

Mud/thatch		1	Asbestos		4
Wood		2	Other		5
Steel		3			

22 DON'T ASK, OBSERVE: Is the house gated?

No		1
Yes		2

23 What is the name of the Health Centre you go to? _____

24 How long does it take to get to your Health Centre (one way journey) Hours ☐☐ : Minutes ☐☐

25 How do you make this journey? On foot ☐ 1 Bus ☐ 2 Other ☐ 3

WASH FACILITIES

1 What is the main source of drinking water for your household?
Tick one only

Piped water inside home	☐	1 --> GO TO QU3
Piped water in yard/plot	☐	2 --> GO TO QU3
Public tap / borehole	☐	3
Dug well	☐	4
Surface water (e.g. river)	☐	5
Other	☐	6

2 How long does it take to go there, take water, and come back? Hours ☐☐ : Minutes ☐☐ Don't know (tick) ☐
Enter time in hours and / or minutes, or tick if don't know

3 Do you do anything to the water AT HOME to make it safer to drink?
Do not prompt, record one response only. If they say chlorine, verify that this is at home. If it is at the tap then Select 'No'

No	☐	1
Yes, boil	☐	2
Yes, chlorine	☐	3
Yes, other	☐	4

4 What toilet facility does your household usually use?

Latrine / toilet	☐	1
No latrine (bush or other)	☐	2 **---> Next section**

5 Ask to view the latrine. OBSERVE AND RECORD.
Tick one only

Flush / pour-flush	☐	1
VIP (ventilated improved pit)	☐	2
Pit with slab	☐	3
Pit no slab	☐	4
Not Seen	☐	5 ---> GO TO QU7

6 OBSERVE, DON'T ASK: Is there soap and water <u>by</u> the latrine?
Tick one only

No	☐	1
Water only	☐	2
Soap only	☐	3
Water and soap	☐	4

7 Do you share this toilet with any other households?

No	☐	1
Yes	☐	2 **--> Enter no. of households including this one:** ☐☐

Enter 88 if doesn't know number

8 OBSERVE (OR ASK IF NOT SEEN): How far is your toilet from your house?
Tick one only

Inside house	☐	1
Outside house, on plot	☐	2
On a neighbour's plot	☐	3
Elsewhere	☐	4

DIARRHOEA TREATMENT

Background

1 What day did [NAME] fall ill with diarrhoea? Day: _____

Refer to calendar

2 Is [NAME] still ill with diarrhoea? No ☐ 1 Yes ☐ 2

3 How many days, including the first day, has/did [NAME] suffer from diarrhoea? ☐☐ days

Verify it matches with the DAY they fell ill and today's DAY or last day of diarrhoea before you move on

4 Did you give [NAME] anything AT HOME or from a traditional healer before going to any clinic to treat the diarrhoea when you first saw he/she had diarrhoea?

Do not prompt, select all responses that apply

Rice water	☐	1	Traditional medicine	☐	5
Flagyl	☐	2	Panadol	☐	6
ORS (homemade)	☐	3	Other	☐	7
ORS (sachet)	☐	4	Nothing	☐	8 --> Go to QU6

5 Where did you get this from?

Tick all that apply

Bought it	☐	1	Relative	☐	4
Had at home already	☐	2	Traditional healer	☐	5
Neighbour	☐	3	Other	☐	6

Treatment seeking

6 Did you take [NAME] to a clinic or hospital? No ☐ 1 **--> Go to QU11**

Tick all that apply

Government clinic ☐ 2 **NAME:** _____

Private clinic ☐ 3

Hospital ☐ 4

7 Were you given any of the following medicines for [NAME's] diarrhoea?

Read out responses and tick yes or no for all

	No	Yes
Flagyl	☐	☐
Panadol	☐	☐
ORS	☐	☐
Zinc	☐	☐
Other	☐	☐

8 Were you given a prescription to buy any other medicines?

No ☐ 1 **--> Go to QU11**

Yes ☐ 2

9 Which medicine(s) were you given a prescription for?

Read out all and select yes or no for each

	No	Yes
Flagyl	☐	☐
Panadol	☐	☐
ORS	☐	☐
Zinc	☐	☐
Other	☐	☐

10 Did you ever get this /these medicines? No ☐ 1 Yes ☐ 2

11 If you could use any medicines for diarrhoea what would you choose?

Record up to two responses. Record their FIRST answers.

1 _____ 2 _____

ORS Knowledge

12 What is ORS for? Prompt to get to answer, e.g. If they say "diarrhoea", ask what it does for diarrhoea. Tick all that apply

Never heard of it	☐ 1 --> go to QU 26	Replaces lost water	☐ 5
Stops diarrhoea	☐ 2	Other	☐ 6
Restores energy	☐ 3	Don't know	☐ 7
Prevents dehydration	☐ 4		

13 How long should you keep ORS once made? ☐☐ Hours **OR** ☐☐ Days Don't know ☐

Do not prompt, record one answer for HOURS or DAYS or tick if don't know (TICK)

14 Where can you get ORS from?

Do not read out responses, record all that apply

Clinic	☐ 1	Don't know	☐ 3
Drug store	☐ 2	Other	☐ 4

ORS Usage

15 Have you used ORS before this episode for any of your children? No ☐ 1 **--> Go to QU 17** Yes ☐ 2

16 What type of ORS have you used before?

Homemade	☐ 1
Sachet	☐ 2
Homemade & Sachet	☐ 3

17 Has [NAME] been given any ORS since he/she started having diarrhoea this time? No ☐ 1 **--> Go to QU23** Yes ☐ 2

18 When was [NAME] first given ORS? **Day:** _____

19 WORK OUT: How many days, including day diarrhoea started as Day 1, did the child have diarrhoea before ORS was first given? ☐☐ Days

20 What type of ORS was this?

Tick all that apply.

Homemade	☐ 1 **--> Go to QU23**
Sachet	☐ 2

21 Where did you get the sachets of ORS?

Tick all that apply.

Had at home already	☐ 1
Neighbour	☐ 2
Given at clinic	☐ 3
Bought it	☐ 4

22 Do you have any ORS solution or sachets in the house now?
If yes, ask to see all sachets / solution and record what you observe (select all that apply)

No ☐ 1 **--> Go to QU23**
Yes ☐ 2

22a

ORS sachet(s) seen and intact	☐ 1	--> ☐☐	sachets (enter number)
ORS sachet(s) seen and part-used	☐ 2	--> ☐☐	sachets (enter number)
ORS solution made up	☐ 3		
Not seen (couldn't find / refused)	☐ 4		

ORS Preparation

23 Ask mother if she is willing to prepare ORS for you now. Give her a sachet. Observe and record:

If she boils water you may wish to continue with other questions until water is ready

Water boiled?	Water chlorinated?	Water measured?		Measured 1 litre?	Sachet into cooled water?	Whole sachet?
No ☐	No ☐	No	☐	No ☐	No ☐	No ☐
Yes ☐	Yes ☐	Yes (after boiling)	☐	Yes ☐	Yes ☐	Yes ☐
		Yes (before boiling)	☐		NA (not boiled) ☐	
		Yes (water not boiled)	☐			

24 Ask mother whether she has any 1L or 500ml containers. Ask to see them, only record what you SEE.

	No	Yes
1L container(s)	☐	☐
500ml container(s)	☐	☐

ORS Attitudes and Beliefs

25 To what extent do you agree with the following statements? This is your opinon and is not right or wrong.
Read out statements and answers, tick relevant box.

		Agree	Disagree	Don't know
a	I think my neighbours always give ORS when their children have diarrhoea			
b	It makes me upset if my neighbours don't know how to make ORS correctly			
c	Knowing how to prepare ORS correctly helps me to belong in my community			
d	I cannot make a litre of ORS because my child will not finish it in one day			
e	My child can get better from diarrhoea without taking any ORS			
f	ORS in the drug store is too expensive for me to buy			
g	I think my neighbours would gossip about me if I didn't give ORS each time my child gets diarrhoea			
h	I try to give ORS every time my child has diarrhoea			
i	I think my neighbours would gossip about me if I did not know how to prepare ORS correctly			

Zinc Knowledge

26 Have you heard of zinc? [show tablets/package] No ☐ 1 --> If no, go to Intervention Exposure section
Yes ☐ 2

27 Other than at the clinic, please tell me all the PLACES you have heard about zinc? Anywhere else?

1	3	5
2	4	6

28 Other than a nurse or clinical officer at the clinic, please tell me all the PEOPLE who have talked to you about zinc? Anyone else?

1	3	5
2	4	6

29 Where can you get zinc from?
Do not read out responses, record all that apply

Clinic ☐ 1 Don't know ☐ 3
Drug store ☐ 2 Other ☐ 4

30 Should zinc be given together with any other treatment?
Tick one only

No ☐ 1 **--> go to qu 32**
Yes ☐ 2
Don't know ☐ 3

31 What should zinc be given with?
Do not read out responses, record all that apply

Flagyl ☐ 1 Panadol ☐ 3
ORS ☐ 2 Other ☐ 4

Zinc Usage

32 Have you used zinc for one of your children before? No ☐ 1 Yes ☐ 2

33 Have you been given or bought [NAME] any zinc to treat this episode of diarrhoea?

No ☐ 1
Yes ☐ 2 --> Exposure section if NO

34 Where did you get this zinc from?
Read out responses and record

Public clinic ☐ 1 Neighbour ☐ 4
Private clinic ☐ 2 Left-over (in house already) ☐ 5
Pharmacy ☐ 3 Other ☐ 6

35 How many tablets did you receive? ☐☐ Don't know (tick) ☐ **Syprup (tick)** ☐

36 Were you given any instructions about when and how to give this medicine? No ☐ 1 Yes ☐ 2

If yes, what: _____

37 How long were you told / do you think you are supposed to give zinc for?
Do not read out options, record one response only.

Whole course ☐ 1
Until better ☐ 2
Don't know ☐ 3
Other ☐ 4

38 Has [NAME] been given any of this zinc?

No ☐ 1 --> If no, go to Exposure section
Yes ☐ 2

39 Are you still giving the tablets? No ☐ 1 Yes ☐ 2

40 Ask to see the Zinc. How many tablets have been taken? Seen ☐ 1 Not seen ☐ 2

40a No. Tablets taken ☐☐ **of** ☐☐ **Or tick if syprup** ☐

Zinc Attitudes and Beliefs

41 To what extent do you agree with the following statements? This is your opinion and is not right or wrong.
Read out statements and answers, tick relevant box.

		Agree	Disagree	Don't know
a	Zinc doesn't work as well as flagyl or other medicine for stopping diarrhoea			
b	I think my neighbours do not give their child zinc when they have diarrhoea			
c	Zinc in the drug store is too expensive for me to buy			
d	I think I should give zinc each time my child has diarrhoea			
e	I think that giving zinc when my child has diarrhoea helps me to belong in the community			
f	I think my neighbours would gossip about me if I don't give my child zinc when they have diarrhoea			
g	I want to give zinc to my child if they have diarrhoea			
h	Zinc stops diarrhoea in my child fast			
i	I think my neighbours do not know about zinc medicine for diarrhoea			

INTERVENTION EXPOSURE

1 My neighbours will gossip about me if I don't know how to take care of my child properly: Agree ☐ 1 Disagree ☐ 2

2 It matters to me if my neighbours gossip about me Agree ☐ 1 Disagree ☐ 2

Brand awareness

3 ***Show Komboni housewives sticker.*** **Ask: Have you ever been given one of these. Can you show me it?**

No sticker ☐	1
Sticker given, not seen ☐	2
Sticker given, seen ☐	3

4 ***Show Komboni housewives logo on the sticker.*** **Ask: have you seen this picture before?**

No ☐	1
Yes ☐	2

5 ***Show picture of Komboni Housewives.*** **Have you heard of Komboni Housewives?**

No ☐	1 **--> END**
Yes ☐	2

6 What topics do the Komboni Housewives talk about?
Do not prompt, select all responses given

Breastfeeding ☐	1
Handwashing ☐	2
Infant feeding ☐	3
ORS ☐	4
Zinc ☐	5
Diarrhoea ☐	6
Don't know ☐	7

7 Is it important for you to be thought of like one of the Komboni Housewives?

No ☐	1
Yes ☐	2

8 Do the Komboni Housewives give useful advice on looking after children?

No ☐	1
Yes ☐	2

9 The Komboni Housewives say '*tiku cheking'ani* and that people will gossip about you if you do not look after your child in the right way. Do you think that this really happens around here?

No ☐	1
Yes ☐	2

10 Do you agree with the komboni housewives that mixed feeding a baby before six months is REALLY something that causes neighbours to gossip about someone?

No ☐	1
Yes ☐	2
Don't know ☐	3

11 Do you agree with the komboni housewives that not washing hands after the toilet is REALLY something that causes neighbours to gossip about someone?

No ☐	1
Yes ☐	2
Don't know ☐	3

12 Do you agree with the komboni housewives that not knowing how to make ORS correctly is REALLY something that causes neighbours to gossip about someone?

No ☐	1
Yes ☐	2
Don't know ☐	3

13 Do you agree with the komboni housewives that not knowing about zinc medicine for diarrhoea is REALLY something that causes neighbours to gossip about someone?

No ☐	1
Yes ☐	2
Don't know ☐	3

Intervention attendance

Radio

14 Have you listened to the radio in the last week?
Read out all options and select one only

- No ☐ 1
- Yes, once ☐ 2
- Yes, more than once ☐ 3 ☐☐ times

15 Do you ever listen to any of these radio stations?

- ☐ Radio 1
- ☐ Komboni FM

16 Have you ever heard a radio show about the komboni housewives?

- No ☐ 1 --> Go to Qu18
- Yes, once ☐ 2
- Yes, more than once ☐ 3 ☐☐ times

17 Did you ever call in to this programme?

- No ☐ 1
- Yes ☐ 2

Forums

18 Did you ever go to a group with other women at someone's home that was led by the komboni housewives?

- No ☐ 1 --> Go to Qu21
- Yes ☐ 2

19 What was the name of the woman who hosted the group? _____

20 Did you receive a certificate? May I see it?

- No certificate received ☐ 1
- Certificate received but not seen ☐ 2
- Certificate received and seen ☐ 3

Date on certificate: ☐☐ Day ☐☐ Month

ORS Corner at Clinic

21 Did you ever attend a session at the clinic led by an NHC that mentioned komboni housewives?

- No ☐ 1 --> Go to Qu26
- Yes ☐ 2 **Clinic name:** _____

22 Which topics did the NHCs talk about?
Do not prompt, select all responses given

- Breastfeeding ☐ 1
- Handwashing ☐ 2
- Infant feeding ☐ 3
- ORS preparation ☐ 4
- ORS (general) ☐ 5
- Zinc ☐ 6
- Diarrhoea ☐ 7
- Don't know ☐ 8

23 Did you receive a certificate and may I see it?

- No certificate given ☐ 1
- Certificate given but not seen ☐ 2
- Certificate given and seen ☐ 3

Date on certificate: ☐☐ Day ☐☐ Month

24 Did your child have diarrhoea at the time you attended this session?

- No ☐ 1
- Yes ☐ 2

25 ASK if you HAVE NOT seen a certificate: Do you remember when you went to this session?

				Don't know (tick)
Day		Month		

Road Show

26 Did you ever attend a large community event with Afunika and the komboni housewives?

No		1 --> Go to Qu28
Yes		2

27 What topics were talked about at this event?

Do not prompt, select all responses given

Breastfeeding		1
Handwashing		2
Infant feeding		3
ORS preparation		4
ORS (general)		5
Zinc		6
Diarrhoea		7
Don't know		8

ORS corner prize draw

28 Did you ever attend a prize draw at the clinic that was run by the NHCs and to do with komboni housewives?

No		1 --> Go to Qu 30
Yes		2

29 Were the Komboni housewives present at this draw?

No		1
Yes		2

30 As far as you known, has anyone that you live with attended a komboni housewife event?

No		1 --> END
Yes		2

31 Which event did they attend?

Read out all options, select all that apply. Record even if different family members attended.

Women's group		1
NHC clinic session		2
Road Show		3
Prize draw		4
Don't know		5

NB: The following four pages were substituted for the pages on ORS and zinc in the survey used to measure exclusive breastfeeding and handwashing with soap

INFANT FEEDING

1 Where did you give birth to [NAME]?
Tick one only

At home	☐	1
Government hospital	☐	2
Government clinic	☐	3
Private facility	☐	4
Other	☐	5

2 Who delivered [NAME]?
Select all that apply

Relative / neighbour	☐	1
Traditional birth attendant	☐	2
Midwife / trained nurse/ clinical officer	☐	3
Other	☐	4

3 How many antenatal classes did you attend before the birth?
Tick one only

None	☐	1
One	☐	2
More than one	☐	3
Don't know	☐	4

4 How many postnatal visits did you attend at the clinic?
Tick one only

None	☐	1
One	☐	2
More than one	☐	3
Don't know	☐	4

5 Are you currently pregnant?

No	☐	1
Yes	☐	2

Infant feeding practices

6 Think about yesterday. Which of the following has [NAME] eaten and drunk since this time yesterday?
Read out each item to the participant and record no or yes for each.

	NO	YES
Vitamins, medicine		
Plain water		
Sweetened water or Zigolo		
Fruit juice		
Tea		
Maheau or super-shake (or equivalent)		

	NO	YES
Infant formula (e.g. S26)		
Powdered (e.g. Cowbell, Nido) or fresh milk		
Other liquids (e.g. soup)		
Cereal, porridge or cerelac		
Nshima		

Other, specify: _____

7 Has [NAME] ever eaten porridge?

No	☐	1	--> GO TO QU9 IF NO
Yes	☐	2	

8 How old was [NAME] when they first had porridge? ☐☐ months Don't know (tick) ☐
Enter months or tick don't know

9 Has [NAME] <u>ever</u> consumed Maheu or super-shake? No ☐ 1 Yes ☐ 2

10 Have you <u>ever</u> breastfed [NAME]?

No	☐	1	--> GO TO QU12 IF NO
Yes	☐	2	

11 Since this time yesterday, have you breastfed [NAME]? No ☐ 1 Yes ☐ 2

12 To what extent do you agree with the following statements? This is your opinion and is not right or wrong.

	Read out statements and answers, tick rel	Agree	Disagree	Don't know
a	I think my neighbours give their babies food and drink before six months			
b	My child can **not** get satisfied with breast milk alone up to six months			
c	I think mothers should not give their babies any food or drink before six months			
d	Clinic staff advise us to give only breast milk up to six months but they do not do this themselves			
e	If my child is fed on breast milk alone they will not grow as big as a mixed fed baby			
f	People with money give their babies formula before six months			
g	My family members advise me to give my baby food and drink before six months			
h	Feeding porridge to my baby at four or five months would cause my neighbours to gossip about me			
i	My neighbours advise me to give my baby food and drink before six months			
j	I think that only giving breast milk up to six months helps me to belong in the community			
k	If a woman has sores on her nipples it is not possible for her to give her baby only breast milk			
l	I plan to give my baby only breast milk until he/she is six months old			
m	It is not possible for me to give my child only breast milk up to six months because I have to go for work / business			
n	It is disgusting for me to give my baby food or drink before six months			

13 Other than at the clinic, please tell me all the PLACES you have heard messages about giving only breast milk for the first six months? Anywhere else?

1	3	5
2	4	6

14 Other than a nurse or clinical officer at the clinic, please tell me all the PEOPLE who have talked to you about giving only breast milk for the first six months? Anyone else?

1	3	5
2	4	6

Zinc

15 Have you heard of a medicine called zinc? No ☐ 1 --> Go to handwashing section if NO
Yes ☐ 2

16 What is zinc for? (don't prompt)

Diarrhoea treatment	☐ 1
Don't know	☐ 2
Other	☐ 3

HANDWASHING

1 How many times (approx.) did you wash your hands with plain water yesterday?
Tick one only

Not at all	☐	1
Once or twice	☐	2
Many times	☐	3

2 How many times (approx.) did you wash your hands with soap yesterday? ☐☐ **times** don't know ☐
--> Go to QU4 if ZERO TIMES

3 Thinking about the time from when you woke up to when you went to sleep yesterday, when did you wash your hands with soap?
Do not prompt. Record all things that are mentioned by ticking, otherwise leave blank.

Before cooking food	☐	1	Before feeding a child	☐	5	When washing clothes	☐	9
After cooking food	☐	2	After cleaning child's bottom / washing nappies	☐	6	When washing dishes	☐	10
Before eating	☐	3	After using toilet	☐	7	When bathing	☐	11
After eating	☐	4	After sweeping / touching something dirty	☐	8	Other	☐	12

4 Which ONE time do you think is the most important time for you to wash your hands with soap?
Do not prompt. Record ONE TIME ONLY. If they give several times ask which is most important. Record first answer.

Before cooking food	☐	1	Before feeding a child	☐	5	Don't know	☐	9
After cooking food	☐	2	After cleaning up child's faeces	☐	6	Other	☐	10
Before eating	☐	3	After using toilet	☐	7			
After eating	☐	4	After sweeping / cleaning	☐	8			

5 When would you say is the SECOND most important time for you to wash your hands with soap?
Do not prompt. Record ONE TIME ONLY or select "don't know". Record first answer.

Before cooking food	☐	1	Before feeding a child	☐	5	Don't know	☐	9
After cooking food	☐	2	After cleaning up child's faeces	☐	6	Other	☐	10
Before eating	☐	3	After using toilet	☐	7			
After eating	☐	4	After sweeping / cleaning	☐	8			

6 How often do you use just water when washing your hands before eating?
Read responses and record one.

Never	☐	1
Sometimes	☐	2
Every meal	☐	3

7 How often do you use soap when washing your hands before eating?
Read responses and record one.

Never	☐	1
Sometimes	☐	2
Every meal	☐	3

8 How often do you use soap when washing your hands after toilet?
Read responses and record one.

Never	☐	1
Sometimes	☐	2
Every time	☐	3

Can you show me how you wash your hands if you want to use soap or soapy water after the toilet?

9 OBSERVE HOW THEY HANDWASH AND RECORD: What is used for handwashing?
Tick one only

Bucket or bowl	☐	1	Handwashing station	☐	3	Other	☐	5
Sink	☐	2	Water tap / borehole	☐	4			

10 OBSERVE HOW THEY HANDWASH AND RECORD: Where is water taken from?

Tick one only

Stored water	☐	1	Sink/tap inside house	☐	3	Other	☐ 5
Bucket/bowl	☐	2	Tap/borehole in yard	☐	4		

11 OBSERVE HOW THEY HANDWASH AND RECORD: Where is soap taken from?

Tick one only

Inside house	☐	1	Soapy water is used	☐	3	No soap in house	☐ 5
Within the yard	☐	2	Other	☐	4		

12 Do you ever ask anyone else in your household to wash their hands using soap? No ☐ 1 **--> to QU14**
Yes ☐ 2

13 Tell me who you ask?

Select all that apply, prompt each time someone is mentioned by saying "anyone else?"

Mother	☐	1	Sibling	☐	4
Father	☐	2	Child	☐	5
Husband	☐	3	Other	☐	6

14 Does anyone ever tell you to wash your hands with soap? No ☐ 1 **--> go to QU16**
Yes ☐ 2

15 Tell me who asks you?

Select all that apply, prompt each time someone is mentioned by saying "anyone else?"

Mother	☐	1	Sibling	☐	4
Father	☐	2	Child	☐	5
Husband	☐	3	Other	☐	6

16 If you run out of soap are you able to make the choice to replace it on your own? No ☐ 1 Yes ☐ 2

17 To what extent do you agree with the following statements? This is your opinion and is not right or wrong.

Read out statements and answers, tick relevant box.

		Agree	Disagree	Don't know
a	I would like to wash my hands with soap all the time after the toilet but sometimes I can't because we do not have any soap			
b	I think my neighbours **do not** usually wash their hands with soap before eating			
c	Going to the toilet and not using soap to wash my hands afterwards would cause my neighbours to gossip about me			
d	I sometimes forget to wash my hands with soap after using the toilet			
e	I think my neighbours **do not** wash their hands with soap after using the toilet all the time			
f	After the toilet I have to wash my hands using soap because otherwise I find it disgusting			
g	I can sometimes go the whole day without washing my hands with soap			
h	I find it disgusting to shake a neighbour's hand if they haven't washed their hands with soap after the toilet			
i	I don't like to wash hands with soap before eating because they smell of soap			
j	Not washing my hands with soap before eating nshima would cause my neighbours to gossip about me			
k	I think that washing hands with soap helps me to belong in the community			

18 Other than at the clinic, please tell me all the PLACES you have heard about handwashing with soap?

1	3	5
2	4	6

19 Other than a nurse or clinical officer at the clinic, please tell me all the PEOPLE who have talked to you about handwashing with soap? Anyone else?

1	3	5
2	4	6

Appendix C: Structured observation tool at baseline and endline in the cluster randomised trial

STRUCTURED OBSERVATION RECORD FORM

Date ☐☐ (Day) ☐☐ (Month) ☐☐ (Year) Cluster: _____ Loc ID ☐☐ FW ID ☐☐ HH ID ☐☐ QC ☐☐

	Time	Event 1 = Before eating; 2 = before giving child food or drink; 3 = Before food prep; 4 = after latrine; 5 = after cleaning child's faeces; 6 = handwash at other time	Person doing event 1 = Man; 2 = Woman; 3 = School-age child (5-18yrs) 4 = Pre-school age child (under-five)	Action taken 1 = no action; 2 = washed hands with water; 3 = washed hands with soap; 4 = washed hands in soapy water; 5 = didn't see	Description of event If hands washed include the location and objects used; If a child is fed anything indicate what food was given (e.g. Breast milk, porridge) and the age of the child.
1		1 2 3 4 5 6	1 2 3 4	1 2 3 4 5	
2		1 2 3 4 5 6	1 2 3 4	1 2 3 4 5	
3		1 2 3 4 5 6	1 2 3 4	1 2 3 4 5	
4		1 2 3 4 5 6	1 2 3 4	1 2 3 4 5	
5		1 2 3 4 5 6	1 2 3 4	1 2 3 4 5	
6		1 2 3 4 5 6	1 2 3 4	1 2 3 4 5	
7		1 2 3 4 5 6	1 2 3 4	1 2 3 4 5	
8		1 2 3 4 5 6	1 2 3 4	1 2 3 4 5	
9		1 2 3 4 5 6	1 2 3 4	1 2 3 4 5	
10		1 2 3 4 5 6	1 2 3 4	1 2 3 4 5	

Appendix D: Selection of process evaluation tools

NB: The following three forms were used to monitor implementation of ORT Corner sessions

ORT CORNER "CIRCLE OF MOTHERS" IMPLEMENTATION RECORD FORM

Date: ☐☐ ☐☐ ☐☐ (Day Month Year) **District:** _____ **Clinic:** _____

NHC Name: _____ **NHC Name:** _____

Day's Session Number: ☐ Start Time: ☐☐ : ☐☐ End Time: ☐☐ : ☐☐

No. of **mothers** present at end of session: ☐☐ No. of **other female caregivers** present at end of session: ☐☐

No. of **fathers** present at end of session: ☐☐

No. Mothers attending any of session with child under six-months: ☐☐

No. of **bottles** given out: ☐☐ No. of **stickers** given out: ☐☐☐ No. of **badges** given out: ☐☐☐

No. of participants who made ORS: ☐☐

SESSION DELIVERY

Was the session conducted as planned? No ☐ Yes ☐ Reason if No (what wasn't done):	Did you have all the supplies you needed? No ☐ Yes ☐ Reason if No (what wasn't done):
What went well or made this session easier to run?	
What did not go so well or was challenging?	
Please record any comments from participants that were interesting or unusual	
Do you have any other comments on how the session went or how the participants responded?	

Name of person completing form: _____ Signature: _____

ORT CORNER "CIRCLE OF MOTHERS" OBSERVATION FORM

Date: ☐☐ ☐☐ ☐☐ District: _____ Clinic: _____

Day Month Year

NHC Name: _____ NHC Name: _____

Day's Session Number: ☐☐ Start Time: ☐☐ : ☐☐ End Time: ☐☐ : ☐☐

No. of **mothers** present at end of session: ☐☐ No. of **other female caregivers** present at end of session: ☐☐

No. of **fathers** present at end of session: ☐☐

SET-UP

Comments on supplies:	Comments on location and how participants were arranged:

SESSION DELIVERY

	Comments	
Introduction section		
Parenting disasters discussion		
Komboni Housewifes introduction		
ORS discussion		
ORS demonstration		
Feeding practices discussion		
"Baby tummy" demonstration		
Zinc		
Participants making ORS	No. Made ORS: _____	
Prize draw		
Use of "nxa nxa nxa"		
Comments on how the NHCs ran the session		
Comments on how engaged participants were with the session (e.g. did they seem bored, attentive, excited)		

ORT CORNER "CIRCLE OF MOTHERS" PARTICIPANT PAIRED INTERVIEW

Date: ☐☐ ☐☐ ☐☐ (Day / Month / Year) **District:** _____ **Clinic:** _____

Day's Session Number: ☐ Start Time: ☐☐ : ☐☐ End Time: ☐☐ : ☐☐

Participant details

	Participant 1	Participant 2
No. Of children under-five		
No. Of children under six-months		

What did you **like most** about this event and why?
What **didn't you like** about this event and why?
How would you explain what you did today to a friend or relative who wasn't here?
What do you think the main message was? Do you agree with it?

How would you measure 1 litre for ORS in your home?	☐	Able to explain convincingly
	☐	Not able to explain convincingly

How did the baby tummy demonstration make you feel and why?

What is a Komboni Housewife?	☐	Able to describe	Comment:
	☐	Not able to describe	

	Yes	No	Reason
Did you find the session too long?			
Did you find it easy to understand the discussion?			
Did anything upset or anger you?			
Was anything boring?			
Do you feel the NHCs were respectful of people's views?			

NB: The below topic guide is one of many used in the process evaluation

Focus group discussion topic guide: Komboni Housewives

- **INTRO:** please tell me your experience of being a komboni housewife, running the forums, running the ORS draws, doing the TVCs, and running the road shows, including highlights and any challenges you faced.
- **FIDELITY**
    - Do you think the content of the forum (messaging, skits (HWWS, baby tummy demo and ORS demo) that we designed was done in a way that that the audience could understand? Which aspects, if any, did they struggle to follow? Which aspects did you have difficulties communicating? Which things did you need to modify from the guide to help participants understand them better?
    - What changes were there over time in how you ran the forums? When were these changes made and how often? Do you remember specifically what made you think of making these changes? What information did you add in that was not in the guide?
    - How did performing in rural areas affect the way the forum was run? How did performing in urban areas affect the forum was run? Note the differences.
    - What differences did you see within the peri-urban areas (densely populated areas) when conducting the forums? Do you think all forums had the same level of quality (delivered to the same standard) and contained all the same content? If not, what affected how well they could be delivered and the way the topics were covered?
    - What differences did you see within the rural areas (densely populated areas) when conducting the forums? Do you think all forums had the same level of quality (delivered to the same standard) and contained all the same content? If not, what affected how well they could be delivered and the way the topics were covered?
    - What do you think affected how well an individual forum was run?
    - What about the materials that you needed (stickers, certificates etc.), how often were these materials available?
    - Was there any topic that wasn't included in the forum scripts that you ended up talking about because the participants asked you to, or things that they asked questions about that were outside the script? What are these things? Why do you think they asked them? Were you able to answer them clearly?
    - What do you think CIDRZ/ your supervisors could have done to help you ensure the sessions were run the best way they could be run?
    - Did the tasks you were expected to perform on a daily basis make it difficult to do your job well? your work load affect the running of the

forums – please be honest so we know what actually affected the sessions in reality
    - If I were to ask you whether the road shows were "successful" what comes to mind to define success for you? Which of the road shows do you think went the best / was the most effective and why? Which went the worst / was the most ineffective and why? Can you rank the road shows in terms of success as you view them? Are there any other challenges you faced that we haven't discussed? Was it more or less challenging to set up the road shows and gain enthusiasm in the community in rural or peri-urban settings? Why? Did you notice any differences in the different road shows between how much the audience seemed to be engaged with and participate in the road shows?
    - How did the draws differ in each setting in terms of how well they were run and attended by members of the community? Did they all cover the same content? Which do you think was the most "successful" / effective, and why? The worst?
- **RECRUITMENT**
    - Describe the process of recruitment for the forums and how these differed in rural and urban settings.
    - How did the different locations of the forum affect attendance or attention levels of the participants if there was any difference? How did they affect the type of participant that attended? Challenges in each area?
    - What reaction did you get when you moved around the community? Were people hostile or welcoming or neutral? Describe this reaction in the initial stage and the final stage. If there are any differences, explain why you think there was a difference.
- **ACCEPTABILITY (OF THE WORK TO THE KHS)**
    - Describe your favourite forum to deliver as a group (give the group 2mins to discuss). Why was this your favourite? Same for roadshows…
    - Describe your worst forum to deliver as a group (give the group 2mins to discuss). Why was this your worst? Same for roadshows…
    - Do you feel satisfied with the resources you had available to you during the programme in terms of the transport and the items you used in the forums, draws and road shows and the items given to participants?
    - How, if at all, do you think this work has affected your own behaviour or change anything about you?
- **ACCEPTABILITY (VIEW OF KHS ON PARTICIPANTS' RESPONSES TO PROGRAMME)**
    - What techniques did you use to keep your participant attentive and participating? Did you find it hard to keep the attention of your participants? Was it hard to retain participants throughout the whole forum? What were the reasons?

- Which part of the forum did the participants respond the best to (i.e. seem the most excited, attentive, ask the most questions?) What do you think CIDRZ should have removed or added in to the sessions?
    - What about the road show / draws?
- If we asked the participants a year later what they remember about the intervention, which topics or aspects do you think they will be able to talk about and why?
- How do you think people respond to the Komboni Housewives programme – is it positive reaction, do you think they want to be part of the komboni housewives? When you say "Tiku cheking 'ani" do you think people really believe that people are watching what they are doing in the community?
- What are some of the positive and negative comments you received from your participants about the forums/roadshows/draws?